

**DOCUMENTS AVAILABLE FROM  
the CENTER for BIOLOGICS EVALUATION and RESEARCH**

**Office of Communication, Training and Manufacturers Assistance, HFM-43  
1401 Rockville Pike   Rockville, MD 20852-1448   301-827-1800   1-800-835-4709**

**FAX Information System 1-888-CBER-FAX or 301-827-3844**

**01-Jun-01**

| <b><i>Hard<br/>Copy</i></b> | <b><i>FAX<br/>ID</i></b> | <b><i>Document<br/>Date</i></b> | <b><i>Title</i></b>   | <b><i>Pages</i></b> |
|-----------------------------|--------------------------|---------------------------------|---|---------------------|
| <u><b>Approval</b></u>      |                          |                                 |   |                     |
| D0692                       | 0692                     | 04/01/99                        | First Biologic Approved for Clotting Disorder - Talk Paper  | 1                   |
| D0674                       | 0674                     | 02/05/99                        | FDA Approves Novel Treatment for Rare Form of Cancer (Talk Paper)   | 2                   |
| D0661                       | 0661                     | 12/21/98                        | FDA Approves First Lyme Disease Vaccine (Talk Paper)  | 2                   |
| D0640                       | 0640                     | 11/02/98                        | First Biotechnology Product For Arthritis Approved - Talk Paper   | 2                   |
| D0625                       | 0625                     | 09/25/98                        | HHS News - New Monoclonal Antibody Approved for Advanced Breast Cancer  | 2                   |
| D0613                       | 0613                     | 08/31/98                        | New Oral Rotavirus Vaccine Helps Prevent Severe Childhood Diarrhea and Vomiting   | 1                   |
| D0611                       | 0611                     | 08/24/98                        | First Treatment for Crohn's Disease Approved  | 1                   |
| D0578                       | 0578                     | 06/03/98                        | FDA Clears New Hepatitis C Treatment for Marketing  | 2                   |
| D0558                       | 0558                     | 05/06/98                        | FDA Approves Alternative to Fresh Frozen Plasma   | 2                   |
| D0556                       | 0556                     | 05/01/98                        | New Fibrin Sealant Approved to Help Control Bleeding in Surgery   | 1                   |
| D0500                       | 0500                     | 12/11/97                        | New Biotechnology Product Approved to Help Prevent Rejection of Kidney Transplants - Daclizumab (Zenapax), Hoffman-La Roche Inc., 12/10/97            | 3                   |
| D0496                       | 0496                     | 11/26/97                        | First Monoclonal Antibody Approved to Treat Cancer - Rituximab (Rituxan), Genentech, Inc., 11/26/97   | 3                   |
| D0495                       | 0495                     | 11/25/97                        | New Biotech Product Approved to Reduce Need for Chemotherapy-Related Platelet Transfusions - Oprelvekin (Neumega), Genetics Institute, Inc., 11/25/97 | 2                   |
| D0461                       | 0461                     | 08/25/97                        | FDA Grants Accelerated Approval to Help Repair Damaged Knee Cartilage (Approved 8/22/97)  | 3                   |

| <i>Hard<br/>Copy</i>     | <i>FAX<br/>ID</i> | <i>Document<br/>Date</i> | <i>Title</i>  | <i>Pages</i> |
|--------------------------|-------------------|--------------------------|---|--------------|
| D0366                    | 0366              | 02/12/97                 | FDA Talk Paper: New Recombinant Product for Hemophilia B - Coagulation Factor IX (Recombinant), BeneFix, Genetics Institute, Inc.   | 2            |
| D0300                    | 0300              | 05/17/96                 | FDA Talk Paper: FDA Approves Second Interferon for Multiple Sclerosis   | 2            |
| D0297                    | 0297              | 05/14/96                 | HHS News - FDA Approves First HIV Home Test System; Backgrounder: Home Use HIV Test Kits  | 6            |
| D0269                    | 0269              | 01/19/96                 | HHS News - Approval Letter: FDA Licenses First Product to Prevent Serious RSV Disease - Respiratory Syncytial Virus Immune Globulin Intravenous (Human)   | 5            |
| D0225                    | 0225              | 07/23/95                 | HHS News - Approval Letter: Interferon beta-1b (Betaseron) Approval   | 7            |
| D0210                    | 0210              | 03/17/95                 | HHS News - Approval Letter: Varicella Virus (Chicken Pox) Vaccine Approval  | 6            |
| D0191                    | 0191              | 12/23/94                 | Statement on FDA Approval of AIDS Virus Test System Based on Oral Fluid Samples   | 2            |
| <i><u>Article</u></i>    |                   |                          |   |              |
| D0333                    |                   | 09/01/96                 | Health Line Information - Online  | 4            |
| D0007                    |                   |                          | Information and Use of Antivenoms   | 1            |
| D0008                    |                   |                          | Summary of Steps to be Taken When Importing Antivenom   | 1            |
| <i><u>Blood Memo</u></i> |                   |                          |   |              |
| D0350                    | 0350              | 12/11/96                 | Revised Precautionary Measures to Reduce the Possible Risk of Transmission of Creutzfeldt-Jakob Disease (CJD) by Blood and Blood Products   | 11           |
| D0351                    | 0351              | 12/11/96                 | Interim Recommendations for Deferral of Donors at Increased Risk for HIV-1 Group O Infection  | 3            |
| D0311                    | 0311              | 07/19/96                 | Recommendations for the Quarantine and Disposition of Units from Prior Collections from Donors with Repeatedly Reactive Screening Tests for Hepatitis B Virus (HBV), Hepatitis C Virus (HCV) and Human T-Lymphotropic Virus Type I (HTLV-I) | 8            |
| D0304                    | 0304              | 05/29/96                 | Recommendations and Licensure Requirements for Leukocyte-Reduced Blood Products   | 12           |
| D0299                    | 0299              | 05/16/96                 | Additional Recommendations for Testing Whole Blood, Blood Components, Source Plasma and Source Leucocytes for Antibody to Hepatitis C Virus Encoded Antigen (Anti-HCV)  | 3            |

| <i>Hard<br/>Copy</i> | <i>FAX<br/>ID</i> | <i>Document<br/>Date</i> | <i>Title</i>   | <i>Pages</i> |
|----------------------|-------------------|--------------------------|--|--------------|
| D0284                | 0284              | 03/14/96                 | Additional Recommendations for Donor Screening With a Licensed Test for HIV-1 Antigen  | 6            |
| D0254                | 0254              | 12/04/95                 | Donor Deferral Due to Red Blood Cell Loss During Collection of Source Plasma by Automated Plasmapheresis   | 2            |
| D0249                | 0249              | 11/13/95                 | Guidance Concerning Conversion to FDA-Reviewed Software Products   | 6            |
| D0228                | 0228              | 08/08/95                 | Recommendations for Donor Screening with a Licensed Test for HIV-1 Antigen   | 14           |
| D0229                | 0229              | 08/08/95                 | Precautionary Measures to Further Reduce the Possible Risk of Transmission of Creutzfeldt-Jakob Disease (CJD) by Blood and Blood Products  | 6            |
| D0230                | 0230              | 08/08/95                 | Disposition of Products Derived from Donors Diagnosed with, or at Known High Risk for, Creutzfeldt-Jakob Disease (CJD)   | 3            |
| D0231                | 0231              | 08/08/95                 | Recommendations for Labeling and Use of Units of Whole Blood, Blood Components, Source Plasma, Recovered Plasma or Source Leukocytes Obtained from Donors with Elevated Levels of Alanine Aminotransferase (ALT) | 2            |
| D0219                | 0219              | 06/08/95                 | Recommendations for the Deferral of Current and Recent Inmates of Correctional Institutions as Donors of Whole Blood, Blood Components, Source Leukocytes and Source Plasma                                      | 5            |
| D0208                | 0208              | 03/14/95                 | To All Establishments Performing Red Blood Cell Immunizations: Revised Recommendations for Red Blood Cell Immunization Programs for Source Plasma  | 6            |
| D0205                | 0205              | 03/10/95                 | Revision of 8/27/82 FDA Memo: Requirements for Infrequent Plasmapheresis Donors  | 3            |
| D0197                | 0197              | 02/03/95                 | Timeframe for Licensing Irradiated Blood Products  | 2            |
| D0190                | 0190              | 12/20/94                 | Recommendations to Users of Medical Devices That Test for Infectious Disease Markers by Enzyme Immunoassay (EIA) Test Systems  | 17           |
| D0173                | 0173              | 08/05/94                 | Use of and FDA Cleared or Approved Sterile Docking Device (STCD) in Blood Bank Practices (transmittal memo 8/12/94) (corrects 7/29/94 Memo)  | 9            |
| D0169                | 0169              | 07/26/94                 | Recommendations for Deferral of Donors for Malaria Risk  | 2            |
| D0156                | 0156              | 01/03/94                 | Recommendations for the Invalidation of Test Results When Using Licensed Viral Marker Assays to Screen Donors  | 5            |

| <i>Hard<br/>Copy</i> | <i>FAX<br/>ID</i> | <i>Document<br/>Date</i> | <i>Title</i>   | <i>Pages</i> |
|----------------------|-------------------|--------------------------|--|--------------|
| D0154                | 0154              | 12/22/93                 | Donor Suitability Related to Laboratory Testing for Viral Hepatitis and a history of Viral Hepatitis   | 4            |
| D0151                | 0151              | 12/10/93                 | Guidance Regarding Post Donation Information Reports   | 3            |
| D0145                |                   | 09/09/93                 | Changes in administrative procedures   | 1            |
| D0143                | 0143              | 08/19/93                 | Revised Recommendations for Testing Whole Blood, Blood Components, Source Plasma and Source Leukocytes for Antibody to Hepatitis C Virus Encoded Antigen (Anti-HCV)              | 9            |
| D0142                | 0142              | 07/28/93                 | Deferral of Blood and Plasma Donors based on Medications   | 4            |
| D0141                | 0141              | 07/22/93                 | Recommendations Regarding License Amendments and Procedures for Gamma Irradiation of Blood Products  | 20           |
| D0135                |                   | 12/16/92                 | Revision of October 7, 1988 Memo Concerning Red Blood Cell Immunization Programs   | 6            |
| D0133                |                   | 11/04/92                 | Volume Limits for Automated Collection of Source Plasma  | 3            |
| D0132                |                   | 09/28/92                 | Nomenclature for Monoclonal Blood Grouping Reagents  | 2            |
| D0131                |                   | 07/21/92                 | Changes in Equipment for Processing Blood Donor Samples  | 5            |
| D0127                |                   | 04/23/92                 | Exemptions to Permit Persons with a History of Viral Hepatitis Before the Age of Eleven Years to Serve as Donors of Whole Blood and Plasma; Alternative Procedures, 21CFR640.120 | 1            |
| D0128                | 0128              | 04/23/92                 | Revised Recommendations for Testing Whole Blood, Blood Components, Source Plasma and Source Leukocytes for Antibody to Hepatitis C Virus Encoded Antigen (Anti-HCV)              | 11           |
| D0129                |                   | 04/23/92                 | Use of Fluorognost HIV-1 Immunofluorescent Assay (IFA)   | 3            |
| D0130                | 0130              | 04/23/92                 | Revised Recommendations for the Prevention of Human Immunodeficiency Virus (HIV) Transmission by Blood and Blood Products  | 24           |
| D0119                |                   | 12/12/91                 | Clarification of FDA Recommendations for Donor Deferral and Product Distribution Based on the Results of Syphilis Testing  | 5            |

| <i>Hard<br/>Copy</i> | <i>FAX<br/>ID</i> | <i>Document<br/>Date</i> | <i>Title</i>   | <i>Pages</i> |
|----------------------|-------------------|--------------------------|--|--------------|
| D0117                |                   | 09/11/91                 | Disposition of Blood Products Intended for Autologous Use That Test Repeatedly Reactive for Anti-HCV   | 1            |
| D0116                |                   | 09/10/91                 | FDA Recommendations Concerning Testing for Antibody to Hepatitis B Core Antigen (Anti-HBc)   | 9            |
| D0112                |                   | 04/17/91                 | Revision to October 26, 1989 Guideline for Collection of Blood or Blood Products from Donors with Positive Tests for Infectious Disease Markers (High Risk Donors) | 2            |
| D0110                |                   | 03/20/91                 | Deficiencies Relating to the Manufacture of Blood and Blood Components   | 3            |
| D0111                |                   | 03/20/91                 | Responsibilities of Blood Establishments Related to Errors & Accidents in the Manufacture of Blood and Blood Components  | 5            |
| D0109                |                   | 03/15/91                 | FDA Request for Information on Blood Storage Patterns and Red Cell Contamination by Yersinia enterocolitica  | 13           |
| D0103                |                   | 06/21/90                 | Use of Genetic Systems HIV-2 EIA   | 2            |
| D0100                |                   | 02/12/90                 | Autologous Blood Collection and Processing Procedures  | 9            |
| D0095                |                   | 10/04/89                 | Abbott Laboratories' HIVAG-1 Test for HIV-1 Antigen(s) Not Recommended for Use as a Donor Screen   | 2            |
| D0093                |                   | 09/08/89                 | Requirements for Computerization of Blood Establishments   | 3            |
| D0088                |                   | 08/01/89                 | Use of Recombigen HIV-1 Latex Agglutination (LA) Test  | 2            |
| D0087                |                   | 07/06/89                 | HTLV-I Antibody Testing  | 1            |
| D0086                |                   | 03/15/89                 | Guidance for Autologous Blood and Blood Components   | 3            |
| D0085                |                   | 02/01/89                 | Use of Recombigen HIV-1 LA Test  | 2            |
| D0083                |                   | 11/29/88                 | HTLV-1 Antibody Testing  | 15           |
| D0081                |                   | 10/18/88                 | To Manufacturers of HTLV-I Antibody Test Kits: Antibody to Human T-Cell Lymphotropic Virus, Type I (HTLV-I) Release Panel I  | 3            |
| D0077                |                   | 08/26/88                 | To Licensed Manufacturers of Blood Grouping Reagents: Criteria for Exemption of Lot Release  | 1            |
| D0076                |                   | 08/15/88                 | Physician Substitutes  | 2            |

| <i>Hard<br/>Copy</i>         | <i>FAX<br/>ID</i> | <i>Document<br/>Date</i> | <i>Title</i>   | <i>Pages</i> |
|------------------------------|-------------------|--------------------------|--|--------------|
| D0075                        |                   | 07/07/88                 | Discontinuance of Prelicensing Inspection for Immunization Using Licensed Tetanus Toxoid and Hepatitis B and Rabies Vaccines | 1            |
| D0073                        |                   | 04/06/88                 | Control of Unsuitable Blood and Blood Components   | 4            |
| D0074                        |                   | 04/06/88                 | Recommendations for Implementation of Computerization in Blood Establishments  | 2            |
| D0071                        |                   | 12/23/87                 | To Licensed In-Vitro Diagnostic Manufacturers: Handling of Human Blood Source Materials                                      | 2            |
| D0069                        |                   | 12/04/87                 | Extension of Dating Period for Storage of Red Blood Cells, Frozen  | 1            |
| D0067                        |                   | 12/02/87                 | Recommendations for the Management of Donors and Units That Are Initially Reactive for Hepatitis B Surface Antigen (HBsAg)   | 5            |
| D0065                        |                   | 11/25/87                 | Deferral of Donors Who Have Received Human Pituitary-Derived Growth Hormone (CJD Related Deaths)                             | 7            |
| D0058                        |                   | 06/02/86                 | Reduction of the Maximum Platelet Storage Period to 5 Days in an Approved Container  | 1            |
| D0045                        |                   | 12/14/84                 | Plasma Derived from Therapeutic Plasma Exchange  | 2            |
| D0046                        |                   | 12/14/84                 | Equivalent Methods for Compatibility Testing   | 1            |
| D0043                        |                   | 02/28/84                 | Deferral of Blood Donors Who Have Received the Drug Accutane (isotretinoin/Roche); 13-cis-retinoic acid)                     | 1            |
| D0036                        |                   | 03/24/83                 | Recommendations to Decrease the Risk of Transmitting AIDS from Plasma Donors   | 4            |
| D0034                        |                   | 08/27/82                 | Requirements for Infrequent Plasmapheresis Donors  | 1            |
| <i><u>Error/Accident</u></i> |                   |                          |  |              |
| D0959                        | 0959              | 05/25/01                 | Error and Accident Report - FY2000, Annual Summary   | 76           |
| D0919                        | 0919              | 11/30/00                 | Error and Accident Report - FY2000, Summary for Third Quarter  | 23           |
| D0833                        | 0833              | 05/16/00                 | Error and Accident Report - FY2000, Summary for Second Quarter   | 21           |
| D0811                        | 0811              | 02/22/00                 | Error and Accident Report - FY2000, Summary for First Quarter  | 20           |
| D0788                        | 0788              | 11/18/99                 | Error and Accident Report - FY99, Annual Summary   | 73           |
| D0775                        | 0775              | 10/20/99                 | Error and Accident Report - FY99, Summary for Fourth Quarter   | 25           |

| <i>Hard<br/>Copy</i> | <i>FAX<br/>ID</i> | <i>Document<br/>Date</i> | <i>Title</i>   | <i>Pages</i> |
|----------------------|-------------------|--------------------------|--|--------------|
| D0737                | 0737              | 08/01/99                 | Error and Accident Report - FY99, Summary for Third Quarter  | 25           |
| D0698                | 0698              | 04/20/99                 | Error and Accident Report - FY99, Summary for Second Quarter | 25           |
| D0691                | 0691              | 03/23/99                 | Error and Accident Report - FY99, Summary for First Quarter  | 18           |
| D0680                | 0680              | 02/19/99                 | Error and Accident Report - FY98, Annual Summary             | 68           |
| D0679                | 0679              | 02/11/99                 | Error and Accident Report - FY98, Summary for Fourth Quarter | 25           |
| D0619                | 0619              | 08/25/98                 | Error and Accident Report - FY98, Summary for Third Quarter  | 25           |
| D0575                | 0575              | 05/14/98                 | Error and Accident Report - FY98, Summary for Second Quarter | 25           |
| D0559                | 0559              | 05/05/98                 | Error and Accident Report - FY98, Summary for First Quarter  | 18           |
| D0535                | 0535              | 02/19/98                 | Error and Accident Report - FY97, Annual Summary             | 65           |
| D0511                | 0511              | 01/09/98                 | Error and Accident Report - FY97, Summary for Fourth Quarter | 25           |
| D0478                | 0478              | 10/09/97                 | Error and Accident Report - FY97, Summary for Third Quarter  | 25           |
| D0460                | 0460              | 08/13/97                 | Error and Accident Report - FY97, Summary for Second Quarter | 25           |
| D0459                | 0459              | 08/12/97                 | Error and Accident Report - FY97, Summary for First Quarter  | 18           |
| D0357                | 0357              | 12/19/96                 | Error and Accident Report - FY96, Annual Summary             | 66           |
| D0352                | 0352              | 12/06/96                 | Error and Accident Report - FY96, Summary for Third Quarter  | 23           |
| D0353                | 0353              | 12/06/96                 | Error and Accident Report - FY96, Summary for Fourth Quarter | 23           |
| D0317                | 0317              | 08/23/96                 | Error and Accident Report - FY96, Summary for First Quarter  | 17           |
| D0318                | 0318              | 08/23/96                 | Error and Accident Report - FY96, Summary for Second Quarter | 23           |
| D0287                | 0287              | 04/17/96                 | Error and Accident Report - FY95, Annual Summary             | 42           |
| D0265                |                   | 01/04/96                 | Error and Accident Report - FY95, Summary for Fourth Quarter | 17           |

| <i>Hard<br/>Copy</i>           | <i>FAX<br/>ID</i> | <i>Document<br/>Date</i> | <i>Title</i>  | <i>Pages</i> |
|--------------------------------|-------------------|--------------------------|---|--------------|
| D0239                          | 0239              | 09/22/95                 | Error and Accident Report - FY95, Summary for Third Quarter   | 17           |
| D0179                          | 0179              | 10/26/94                 | Error and Accident Report - FY94, Annual Summary  | 22           |
| <i><u>FDA Statement</u></i>    |                   |                          |   |              |
| D0772                          | 0772              | 11/02/99                 | HHS News - Abbott Labs Signs Consent Degree with FDA; Agrees to Correct Manufacturing Deficiencies  | 3            |
| D0401                          | 0401              | 04/26/97                 | Statement on Intermountain Health Care, Inc.  | 1            |
| <i><u>Federal Register</u></i> |                   |                          |   |              |
| D0957                          | 0957              | 05/25/01                 | Guidance for Industry: IND Meetings for Human Drugs and Biologics; Chemistry, Manufacturing and Controls Information  | 2            |
| D0950                          | 0950              | 04/20/01                 | Draft Guidance for Industry on Using FDA-Approved Patient Labeling in Consumer-Directed Print Advertisements; Availability  | 2            |
| D0945                          | 0945              | 04/04/01                 | Draft Guidance for Industry; Reports on the Status of Postmarketing Studies - Implementation of Section 130 of the Food & Drug Administration Modernization Act of 1997; Notice of Availability | 3            |
| D0942                          | 0942              | 03/29/01                 | FR Notice: Guidance for Industry on Monoclonal Antibodies Used as Reagents in Drug Manufacturing; Availability  | 2            |
| D0931                          | 0931              | 02/07/01                 | Draft "Guidance for Industry: Source Animal, Product, Preclinical, and Clinical Issues Concerning the Use of Xenotransplantation Products in Humans;" Notice of Availability                    | 1            |
| D0934                          | 0934              | 01/31/01                 | Draft Guidance for Industry: Pre-Storage Leukocyte Reduction of Whole Blood and Blood Components Intended for Transfusion; Availability   | 2            |
| D0927                          | 0927              | 01/19/01                 | Human Cells, Tissues, and Cellular and Tissue-Based Products; Establishment Registration and Listing - Final Rule   | 23           |
| D0926                          | 0926              | 01/18/01                 | Availability for Public Disclosure and Submission to FDA for Public Disclosure of Certain Data and Information Related to Human Gene Therapy or Xenotransplantation; Proposed Rule              | 19           |
| D0925                          | 0925              | 01/10/01                 | Revisions to the Requirements Applicable to Blood, Blood Components, and Source Plasma; Confirmation in Part and Technical Amendment  | 4            |

| <i>Hard<br/>Copy</i> | <i>FAX<br/>ID</i> | <i>Document<br/>Date</i> | <i>Title</i>   | <i>Pages</i> |
|----------------------|-------------------|--------------------------|--|--------------|
| D0924                | 0924              | 01/08/01                 | Current Good Tissue Practice for Manufacturers of Human Cellular and Tissue-Based Products; Inspection and Enforcement; Proposed Rule  | 52           |
| D0923                | 0923              | 12/29/00                 | ICH Guidance on Q6A Specifications: Test Procedures and Acceptance Criteria for New Drug Substances and New Drug Products: Chemical Substances; Notice   | 54           |
| D0922                | 0922              | 12/22/00                 | Requirements on Content and Format of Labeling for Human Prescription Drugs and Biologics; Requirements for Prescription Drug Product Labels; Proposed Rule  | 51           |
| D0921                | 0921              | 12/20/00                 | Draft Guidance for Industry: Variances for Blood Collection from Individuals with Hereditary Hemochromatosis; Availability   | 2            |
| D0917                | 0917              | 12/12/00                 | Revision to Requirements for Licensed Anti-Human Globulin and Blood Grouping Reagents; Direct final rule   | 3            |
| D0918                | 0918              | 12/12/00                 | Revision to requirements for Licensed Anti-Human Globulin and Blood Grouping Reagents; Companion to Direct Final Rule  | 3            |
| D0914                | 0914              | 12/04/00                 | Draft Guidance for Industry on Recommendations for Complying With the Pediatric Rule: Availability   | 1            |
| D0911                | 0911              | 11/20/00                 | Federal Register Request for Nominations for Voting Members on Public Advisory Committees  | 2            |
| D0907                | 0907              | 11/16/00                 | Current Good Manufacturing Practice for Blood and Blood Components; Notification of Consignees and Transfusion Recipients Receiving Blood and Blood Components at Increased Risk of Transmitting HCV Infection ("Lookback"); Proposed Rule | 40           |
| D0904                | 0904              | 11/09/00                 | Biological Products: Reporting of Biological Product Deviations in Manufacturing; Final Rule; CORRECTION of Effective Date   | 1            |
| D0905                | 0905              | 11/09/00                 | Draft Guidance for Industry on Cancer Drug and Biological Products - Clinical Data in Marketing Applications; Availability   | 2            |
| D0903                | 0903              | 11/07/00                 | Biological Products: Reporting of Biological Product Deviations in Manufacturing; Final Rule   | 15           |
| D0901                | 0901              | 10/30/00                 | Postmarketing Studies for Approved Human Drug and Licensed Biological Products; Status Reports - Final rule  | 13           |

| <i>Hard<br/>Copy</i> | <i>FAX<br/>ID</i> | <i>Document<br/>Date</i> | <i>Title</i>   | <i>Pages</i> |
|----------------------|-------------------|--------------------------|--|--------------|
| D0897                | 0897              | 10/18/00                 | Agency Information Collection Activities; Submission for OMB Review; Comment Request; Public Health Service (PHS) Guideline on Infectious Disease Issues in Xenotransplantation - Notice   | 5            |
| D0893                | 0893              | 10/06/00                 | Regulations Requiring Manufacturers to Assess the Safety and Effectiveness of New Drugs and Biological Products in Pediatric Patients; Technical Amendment; Final Rule   | 1            |
| D0874                | 0874              | 08/29/00                 | Final Rule: Biological Products Regulated Under Section 351 of the Public Health Service Act; implementation of Biologics License; Elimination of Establishment License & Product License; Technical Amendment                       | 1            |
| D0873                | 0873              | 08/28/00                 | Final Rule: Revision of Requirements Applicable to Albumin (Human), Plasma Protein Fraction (Human), and immune Globulin (Human)   | 3            |
| D0872                | 0872              | 08/24/00                 | International Conference on Harmonisation; Draft Guidance on M4 Common Technical Document; Availability  | 4            |
| D0868                | 0868              | 08/07/00                 | International Conference on Harmonisation; Draft Guidance on Safety Pharmacology Studies for Human Pharmaceuticals; Availability   | 2            |
| D0866                | 0866              | 08/01/00                 | International Conference on Harmonisation; Draft Guidance on Good Manufacturing Practice for Active Pharmaceutical Ingredients; Availability   | 2            |
| D0864                | 0864              | 07/31/00                 | Revised Draft Guidance for Industry on Developing Medical Imaging Drugs and Biological Products; Availability  | 4            |
| D0858                | 0858              | 07/18/00                 | Blood Standards: Pilot program for Licensing and Draft "Guidance for Industry: CBER Pilot Licensing Program for Immunization of Source Plasma Donors Using Immunogen Red Blood Cells Obtained from an Outside Supplier; Availability | 2            |
| D0855                | 0855              | 06/28/00                 | Draft Guidance for Industry on Chronic Cutaneous Ulcer and Burn Wounds - Developing Products for Treatment; Availability   | 1            |
| D0850                | 0850              | 06/22/00                 | Temporary Deferment of Activities Relating to Certain Biologics Submissions  | 2            |
| D0846                | 0846              | 06/21/00                 | Draft Guidance for Industry on the Content and Format of the Adverse Reactions Section of Labeling for Human Prescription Drugs and Biologics; Availability  | 2            |
| D0848                | 0848              | 06/21/00                 | Draft Guidance for Industry: Pediatric Oncology Studies in Response to a Written Request; Availability   | 2            |

| <i>Hard Copy</i> | <i>FAX ID</i> | <i>Document Date</i> | <i>Title</i>  | <i>Pages</i> |
|------------------|---------------|----------------------|---|--------------|
| D0835            | 0835          | 06/08/00             | Agency Information Collection Activities; Proposed Collection; Comment Request - CORRECTION   | 6            |
| D0842            | 0842          | 06/08/00             | Draft Guidance for Industry: Recommendations for Donor Questioning Regarding Possible Exposure to Malaria; Availability   | 2            |
| D0838            | 0838          | 06/06/00             | Guidance for Industry: Recognition and Use of a Standard for the Uniform Labeling of Blood and Blood Components; Availability   | 2            |
| D0834            | 0834          | 05/24/00             | Quarterly List of Guidance Documents at the Food & Drug Administration  | 8            |
| D0832            | 0832          | 05/15/00             | Notice of Biological Products: Bacterial Vaccines and Related Biological Products; Implementation of Efficacy Review; Proposed Order  | 8            |
| D0828            | 0828          | 04/12/00             | Notice: International Conference on Harmonisation; E11: Clinical Investigation of Medicinal Products in the Pediatric Population  | 5            |
| D0827            | 0827          | 04/10/00             | Proposed Rule: Amendment of Regulations Regarding Certain Label Statements on Prescription Drugs  | 5            |
| D0825            | 0825          | 03/29/00             | Draft Guidance for Industry on Information Program on Clinical Trials for Serious or Life-Threatening Diseases: Establishment of a Data Bank: Availability                          | 4            |
| D0821            | 0821          | 03/15/00             | Blood Standards; Pilot Program for Licensing Gamma Irradiated Blood and Blood Components and "Guidance for Industry: Gamma Irradiation of Blood and Blood Components;" Availability | 2            |
| D0819            | 0819          | 03/14/00             | Revision of Requirements Applicable to Albumin (Human) Plasma Protein Fraction (Human) and Immune Globulin (Human); Confirmation in Part and Technical Amendment; Final Rule        | 2            |
| D0820            | 0820          | 03/14/00             | Federal Register Quarterly List of Guidance Documents at the Food and Drug Administration   | 15           |
| D0812            | 0812          | 03/07/00             | Guidance for Industry on Formal Meetings with Sponsors and Applicants for PDUFA Products; Availability  | 2            |
| D0814            | 0814          | 03/07/00             | Guidance for Industry on Formal Dispute Resolution: Appeals Above the Division Level; Availability  | 2            |
| D0807            | 0807          | 02/15/00             | Draft Guidance for Reviewers: Potency Limits For Standardized Dust Mite and Grass Allergen Vaccines: A Revised Protocol; Availability   | 2            |
| D0809            | 0809          | 02/11/00             | ICH; M4 Common Technical Document; Request for Comments on Initial Components; Availability   | 4            |

| <i>Hard<br/>Copy</i> | <i>FAX<br/>ID</i> | <i>Document<br/>Date</i> | <i>Title</i>   | <i>Pages</i> |
|----------------------|-------------------|--------------------------|--|--------------|
| D0805                | 0805              | 02/09/00                 | Draft Guidance for Industry on Special Protocol Assessment; Availability   | 4            |
| D0802                | 0802              | 02/08/00                 | Revocation of U.S. License 1116 Bestblood, Ltd   | 2            |
| D0803                | 0803              | 02/04/00                 | Draft Guidance for Industry: IND Meetings for Human Drugs and Biologics; Chemistry, Manufacturing, and Controls Information; Availability  | 2            |
| D0798                | 0798              | 01/12/00                 | New Drug Applications; Drug Master Files; Final Rule   | 5            |
| D0797                | 0797              | 01/05/00                 | Investigational Biological Product Trials; Procedure to Monitor Clinical Hold Process; Meeting of Oversight Committee and Request for Submissions  | 2            |
| D0795                | 0795              | 01/03/00                 | Draft Guidance for Industry: Changes to an Approved Application: Biological Products: Human Blood and Blood Components Intended for Transfusion or for Further Manufacture; Availability   | 2            |
| D0794                | 0794              | 12/30/99                 | Draft Guidance for Industry: Precautionary Measures to Reduce the Possible Risk of Transmission of Zoonoses by Blood and Blood Products From Xenotransplantation Product Recipients and Their Contacts; Availability             | 2            |
| D0793                | 0793              | 12/28/99                 | Establishment of Prescription Drug User Fee Rates for Fiscal Year 2000   | 5            |
| D0791                | 0791              | 12/20/99                 | Guidance for Industry: In the Manufacture and Clinical Evaluation of In Vitro Tests to Detect Nucleic Acid Sequences of Human Immunodeficiency Viruses Types 1 and 2; Availability   | 2            |
| D0786                | 0786              | 12/07/99                 | Draft Guidance for Industry: Pharmacokinetics in Patients With Impaired Hepatic Function: Study Design, Data Analysis and Impact on Dosing and Labeling; Availability  | 1            |
| D0785                | 0785              | 12/01/99                 | Postmarketing Studies for Human Drugs and Licensed Biological Products; Status Reports; Proposed Rule  | 10           |
| D0782                | 0782              | 11/24/99                 | Guidance for Industry: on In Vivo Drug Metabolism / Drug Interaction Studies - Study Design, Data Analysis, and Recommendations for Dosing and Labeling; Availability  | 2            |
| D0780                | 0780              | 11/23/99                 | Guidance for Industry: Revised Precautionary Measures to Reduce the Possible Risk of Transmission of Creutzfeldt-Jakob Disease (CJD) and New Variant Creutzfeldt-Jakob Disease (nvCJD) by Blood and Blood Products; Availability | 2            |
| D0779                | 0779              | 11/19/99                 | Mercury Compounds in Drugs and Food; List and Analysis; Availability   | 27           |

| <i>Hard<br/>Copy</i> | <i>FAX<br/>ID</i> | <i>Document<br/>Date</i> | <i>Title</i>  | <i>Pages</i> |
|----------------------|-------------------|--------------------------|---|--------------|
| D0778                | 0778              | 11/15/99                 | Semiannual Guidance Agenda  | 12           |
| D0776                | 0776              | 11/12/99                 | Guidance for Industry: Providing Regulatory Submissions to the Center for Biologics Evaluation and Research (CBER) in Electronic Format-Biologics Marketing Applications [Biologics License Application (BLA), Product License Application (PLA)/ Establishment | 2            |
| D0770                | 0770              | 11/03/99                 | Draft Guidance for Industry: Supplemental Guidance on Testing for Replication Competent Retrovirus in Retroviral Vector Based Gene Therapy Products & During Follow-up of Patients in Clinical Trials Using Retroviral Vectors; Availability                    | 2            |
| D0767                | 0767              | 10/20/99                 | Biological Products Regulated Under Section 351 of the Public Health Service Act; Implementation of Biologics License; Elimination of Establishment License and Product License; Final Rule   | 14           |
| D0761                | 0761              | 10/05/99                 | New Drugs and Biological Drug Products; Evidence Needed to Demonstrate Efficacy of New Drugs for Use Against Lethal or Permanently Disabling Toxic Substances When Efficacy Studies in Humans Ethically Cannot Be Conducted; Proposed Rule                      | 11           |
| D0762                | 0762              | 10/05/99                 | Human Drugs and Biologics; Determination That Informed Consent Is NOT Feasible or Is Contrary to the Best Interests of Recipients; Revocation of 1990 Interim Final Rule; Establishment of New Interim Final Rule   | 11           |
| D0760                | 0760              | 09/30/99                 | Suitability Determination for Donors of Human Cellular and Tissue-Based Products; Proposed Rule   | 28           |
| D0754                | 0754              | 09/01/99                 | Guidance for Industry: Revised Recommendations for the Invalidation of Test Results When Using Licensed and 510(k) Cleared Bloodborne Pathogen Assays to Test Donors; Availability  | 1            |
| D0752                | 0752              | 08/27/99                 | Guidance for Industry: on Possible Dioxin / PCB Contamination in Drugs and Biological Products; Availability  | 2            |
| D0745                | 0745              | 08/19/99                 | Requirements for Testing Human Blood Donors for Evidence of Infection Due to Communicable Disease Agents; Proposed Rule   | 17           |
| D0746                | 0746              | 08/19/99                 | General Requirements for Blood, Blood Components and Blood Derivatives; Notification of Deferred Donors; Proposed Rule  | 11           |
| D0747                | 0747              | 08/19/99                 | Revisions to the Requirements Applicable to Blood, Blood Components and Source Plasma; Direct Final Rule  | 9            |

| <i>Hard<br/>Copy</i> | <i>FAX<br/>ID</i> | <i>Document<br/>Date</i> | <i>Title</i>  | <i>Pages</i> |
|----------------------|-------------------|--------------------------|---|--------------|
| D0748                | 0748              | 08/19/99                 | Revisions to the Requirements Applicable to Blood, Blood Components and Source Plasma; Companion Document to the Direct Final Rule; Proposed Rule   | 8            |
| D0749                | 0749              | 08/19/99                 | Plasma Derivatives and Other Blood-Derived Products; Requirements for Tracking and Notification; Advance Notice of Proposed Rulemaking  | 4            |
| D0740                | 0740              | 08/17/99                 | Guidance for Industry: Revised Precautionary Measures to Reduce the Possible Risk of Transmission of Creutzfeldt-Jakob Disease (CJD) and New Variant Creutzfeldt-Jakob Disease (nvCJD) by Blood and Blood Products; Availability                                | 2            |
| D0741                | 0741              | 08/17/99                 | Draft Guidance for Industry: Information Request and Discipline Review Letters Under the Prescription Drug User Fee Act; Availability   | 2            |
| D0735                | 0735              | 08/03/99                 | Draft Guidance for Industry: Cooperative Manufacturing Arrangements for Licensed Biologics; Availability  | 2            |
| D0733                | 0733              | 07/26/99                 | Draft Guidance for Industry: Interpreting Sameness of Monoclonal Antibody Products Under the Orphan Drug Regulations; Availability  | 2            |
| D0730                | 0730              | 07/15/99                 | Draft Guidance for Industry: Clinical Development Programs for Drugs, Devices, and Biological Products Intended for the Treatment of Osteoarthritis (OA); Availability  | 2            |
| D0727                | 0727              | 07/07/99                 | Guidance for Industry: on Container Closure Systems for Packaging Human Drugs and Biologics; Chemistry, Manufacturing, and Controls Documentation; Availability   | 2            |
| D0723                | 0723              | 06/28/99                 | Supplements and Other Changes to an Approved Application  | 18           |
| D0720                | 0720              | 06/24/99                 | Draft Guidance for Industry: Monoclonal Antibodies Used as Reagents in Drug Manufacturing; Availability   | 2            |
| D0719                | 0719              | 06/22/99                 | Draft Guidance for Industry: Current Good Manufacturing Practice for Blood and Blood Components: (1) Quarantine and Disposition of Prior Collections from Donors with Repeatedly Reactive Screening Tests for Hepatitis C Virus (HCV); (2) Supplemental Testing | 5            |
| D0714                | 0714              | 06/04/99                 | Draft Guidance for Industry: on Establishing Pregnancy Registries; Availability   | 1            |
| D0715                | 0715              | 06/04/99                 | Draft Guidance for Reviewers: on Evaluation of Human Pregnancy Outcome Data; Availability   | 2            |

| <i>Hard<br/>Copy</i> | <i>FAX<br/>ID</i> | <i>Document<br/>Date</i> | <i>Title</i>   | <i>Pages</i> |
|----------------------|-------------------|--------------------------|--|--------------|
| D0710                | 0710              | 05/20/99                 | Guidance for Industry: Efficacy Studies to Support Marketing of Fibrin Sealant Products Manufactured for Commercial Use  | 2            |
| D0711                | 0711              | 05/20/99                 | Draft Guidance for Industry: For Platelet Testing and Evaluation of Platelet Substitute Products   | 2            |
| D0707                | 0707              | 05/17/99                 | Regulations for In Vivo Radiopharmaceuticals Used for Diagnosis and Monitoring   | 14           |
| D0704                | 0704              | 05/10/99                 | Guidance for Industry: for the Submission of Chemistry, Manufacturing and Controls and Establishment Description Information for Human Blood and Blood Components Intended for Transfusion or for Further Manufacture and For the Completion of the Form FDA 3 | 2            |
| D0700                | 0700              | 04/26/99                 | FDAMA of 1997; List of Documents Issued by FDA That Apply to Medical Devices Regulated by CBER   | 2            |
| D0701                | 0701              | 04/26/99                 | Iatric Corp.; Revocation of US License 0416  | 2            |
| D0697                | 0697              | 04/21/99                 | Investigational New Drug Applications; Clinical Holds; Confirmation of Effective Date; Direct Final Rule   | 1            |
| D0695                | 0695              | 04/20/99                 | Draft Guidance for Industry: on INDs for Phase 2 and 3 Studies of Drugs, Including Specified Therapeutic Biotechnology-Derived Products; Chemistry, Manufacturing and Controls Content and Format; Availability  | 2            |
| D0685                | 0685              | 03/12/99                 | Draft Guidance for Industry: Product Name Placement, Size and Prominence in Advertising and Promotional Labeling   | 2            |
| D0682                | 0682              | 03/08/99                 | Guidance for Industry: Content and Format of Chemistry, Manufacturing and Controls Information and Establishment Description Information for a Biological In Vitro Diagnostic Product; Availability  | 2            |
| D0671                | 0671              | 02/03/99                 | Guidance for Industry: on FDA Approval of New Cancer Treatment Uses for Marketing Drug and Biological Products; Availability   | 2            |
| D0657                | 0657              | 12/14/98                 | Investigational New Drug Applications; Clinical Holds  | 3            |
| D0658                | 0658              | 12/14/98                 | Investigational New Drug Applications; Clinical Holds; Companion Document to Direct Final Rule   | 3            |
| D0656                | 0656              | 12/10/98                 | Product, Establishment, and Biologics License Applications, Refusal to File; Meeting of Oversight Committee  | 1            |

| <i>Hard<br/>Copy</i> | <i>FAX<br/>ID</i> | <i>Document<br/>Date</i> | <i>Title</i>  | <i>Pages</i> |
|----------------------|-------------------|--------------------------|---|--------------|
| D0655                | 0655              | 12/09/98                 | Investigational Biological Product Trials; Procedure to Monitor Clinical Hold Process; Meeting of Review Committee and Request for Submissions  | 2            |
| D0649                | 0649              | 11/24/98                 | FDA Plan for Statutory Compliance   | 42           |
| D0650                | 0650              | 11/24/98                 | Import for Export: Reporting and Recordkeeping Requirements for Unapproved or Violative Products Imported for Further Processing or Incorporation and Subsequent Export; Proposed Rule  | 8            |
| D0645                | 0645              | 11/20/98                 | Dissemination of Information on Unapproved / New Uses for Marketed Drugs, Biologics and Devices; Final Rule   | 34           |
| D0637                | 0637              | 10/30/98                 | Guidance for Industry: on Advisory Committees: Implementing Section 120 of the Food and Drug Administration Modernization Act of 1997; Availability   | 1            |
| D0636                | 0636              | 10/29/98                 | Product and Clinical Development of Tumor Vaccines; Public Workshop   | 2            |
| D0633                | 0633              | 10/21/98                 | Guidance for Industry: Current Good Manufacturing Practices for Blood and Blood Components: (1) Quarantine and Disposition of Units From Prior Collections From Donors With Repeatedly Reactive Screening Tests for Antibody to Hepatitis C Virus (Anti-HCV); (2) Supplemental Testing, and the Notification of Consignees and Blood Recipients of Donor Test Results for Anti-HCV;" Availability | 2            |
| D0634                | 0634              | 10/21/98                 | Antibody to Human T-Cell Lymphotropic Virus Type II (HTLV-II) Reference Panel; Availability   | 2            |
| D0763                | 0763              | 10/08/98                 | Guidance for Industry: on Qualifying for Pediatric Exclusivity; Availability; Revised   | 2            |
| D0627                | 0627              | 10/01/98                 | FDAMA; Allergenic Patch Test Kits; Request for Comments or Data   | 2            |
| D0626                | 0626              | 09/29/98                 | Biosera, Inc.; Revocation of U.S. License No. 1059  | 1            |
| D0604                | 0604              | 09/04/98                 | Revisions to the General Safety Test Requirements for Biological Products   | 1            |
| D0614                | 0614              | 09/04/98                 | Agency Information Collection Activities; Comment Request; Establishment and Product License Applications   | 2            |
| D0608                | 0608              | 08/20/98                 | Public Meeting on Section 406(b) of the Food and Drug Administration Modernization Act of 1997; Notice of Public Meeting  | 2            |

| <i>Hard<br/>Copy</i> | <i>FAX<br/>ID</i> | <i>Document<br/>Date</i> | <i>Title</i>   | <i>Pages</i> |
|----------------------|-------------------|--------------------------|--|--------------|
| D0609                | 0609              | 08/20/98                 | Public Meeting on Section 406(b) of the Food and Drug Administration Modernization Act of 1997; Notice of Public Meeting   | 2            |
| D0606                | 0606              | 08/11/98                 | Biological Products Regulated Under Section 351 of the Public Health Service Act; Implementation of Biologics License; Elimination of Establishment License and Product License; Public Workshop 9/2/98    | 2            |
| D0605                | 0605              | 08/06/98                 | Biotechnology Manufacturing Grassroots Meeting - 9/15/98   | 2            |
| D0603                | 0603              | 07/31/98                 | Biological Products Regulated Under Section 351 of the Public Health Service Act; Implementation of the Biologics License; Elimination of the Establishment License and the Product License; Proposed Rule | 14           |
| D0598                | 0598              | 07/27/98                 | Hematopoietic Stem / Progenitor Cell Products: Discussion of Unrelated Allogeneic Placental / Umbilical Cord Blood and Peripheral Blood Cell Banking and Transplantation; Notice of Public Workshop        | 1            |
| D0599                | 0599              | 07/27/98                 | Granulocytes for Transfusion: Research and Clinical Experience; Public Workshop  | 1            |
| D0600                | 0600              | 07/27/98                 | Evaluation of In Vivo Efficacy of Platelet Transfusion Products and Platelet Substitutes; Public Workshop  | 2            |
| D0601                | 0601              | 07/27/98                 | Draft Guidance for Industry: Recommendations for Collecting Red Blood Cells by Automated Apheresis Methods; Availability   | 2            |
| D0602                | 0602              | 07/27/98                 | Guidance for Industry: on Environmental Assessment of Human Drug and Biologics Applications; Availability  | 2            |
| D0594                | 0594              | 07/24/98                 | Public Meeting on Section 406(b) of the Food and Drug Administration Modernization Act of 1997; Notice of meeting  | 3            |
| D0587                | 0587              | 06/19/98                 | Knickerbocker Biologicals, Inc.; Revocation of US License No. 458-001  | 1            |
| D0580                | 0580              | 06/08/98                 | Dissemination of Information on Unapproved / New Uses for Marketed Drugs, Biologics and Devices; Proposed Rule   | 19           |
| D0574                | 0574              | 05/22/98                 | Regulations for In Vivo Radiopharmaceuticals Used for Diagnosis and Monitoring   | 9            |
| D0564                | 0564              | 05/14/98                 | Guidance for Industry: on Classifying Resubmissions in Response to Action Letters; Availability  | 2            |
| D0566                | 0566              | 05/14/98                 | Guidance for Industry: on Submitting and Reviewing Complete Responses to Clinical Holds; Availability  | 2            |

| <i>Hard<br/>Copy</i> | <i>FAX<br/>ID</i> | <i>Document<br/>Date</i> | <i>Title</i>  | <i>Pages</i> |
|----------------------|-------------------|--------------------------|---|--------------|
| D0568                | 0568              | 05/14/98                 | Establishment Registration and Listing for Manufacturers of Human Cellular and Tissue-Based Products; Proposed Rule   | 12           |
| D0557                | 0557              | 05/06/98                 | Natural Rubber - Containing Medical Devices; User Labeling; Final Rule  | 1            |
| D0553                | 0553              | 04/20/98                 | Revisions to the General Safety Requirements for Biological Products; Direct Final Rule   | 5            |
| D0554                | 0554              | 04/20/98                 | Revisions to the General Safety Requirements for Biological Products; Companion Document to Direct Final Rule; Proposed Rule  | 4            |
| D0551                | 0551              | 04/17/98                 | Draft Guidance for Industry: on Manufacturing, Processing or Holding Active Pharmaceutical Ingredients; Availability  | 2            |
| D0543                | 0543              | 03/20/98                 | Guidance for Industry: Supplemental Testing and the Notification of Consignees of Donor Test Results for Antibody to Hepatitis C Virus (Anti-HCV); Availability   | 2            |
| D0541                | 0541              | 03/18/98                 | Draft Guidance for Industry: on Clinical Development Programs for Drugs, Devices and Biological Products for the Treatment of Rheumatoid Arthritis (RA); Notice of Availability                         | 2            |
| D0526                | 0526              | 02/02/98                 | Developing Regulations for In Vivo Radiopharmaceuticals Used for Diagnosis and Monitoring; Public Meeting   | 2            |
| D0521                | 0521              | 01/28/98                 | Draft Guidance for Industry: Container and Closure Integrity Testing in Lieu of Sterility Testing as a Component of the Stability Protocol for Sterile Products; Availability                           | 2            |
| D0518                | 0518              | 01/26/98                 | Draft Guidance for Industry: Efficacy Studies to Support Marketing of Fibrin Sealant Products Manufactured for Commercial Use   | 3            |
| D0517                | 0517              | 01/20/98                 | Request for Proposed Standards for Unrelated Allogeneic Peripheral and Placental/Umbilical Cord Blood Hematopoietic Stem/Progenitor Cell Products; Request for Comments                                 | 4            |
| D0509                | 0509              | 01/05/98                 | Draft Guidance for Industry: Promoting Medical Products in a Changing Healthcare Environment; I. Medical Product Promotion by Healthcare Organizations or Pharmacy Benefits Management Companies (PBMS) | 4            |
| D0501                | 0501              | 12/15/97                 | Product, Establishment, and Biologics License Applications, Refusal to File; Meeting of Oversight Committee   | 1            |

| <i>Hard<br/>Copy</i> | <i>FAX<br/>ID</i> | <i>Document<br/>Date</i> | <i>Title</i>  | <i>Pages</i> |
|----------------------|-------------------|--------------------------|---|--------------|
| D0502                | 0502              | 12/15/97                 | Investigational Biological Product Trials; Procedure to Monitor Clinical Hold Process; Meeting of Oversight Committee and Request for Submissions                   | 2            |
| D0498                | 0498              | 12/09/97                 | Establishment of Prescription Drug User Fee Rates for Fiscal Year 1998  | 3            |
| D0491                | 0491              | 11/25/97                 | Intermountain Health Care, Inc; Revocation of U.S. License No. 0729   | 1            |
| D0490                | 0490              | 11/14/97                 | Iatric Corporation; Revocation of Product License for Coccidioidin, USP (BioCox)  | 2            |
| D0485                | 0485              | 11/03/97                 | Current Topics in Immunohematologic Testing; Public Workshop 12/10/97   | 1            |
| D0484                | 0484              | 10/29/97                 | Biologics License Application for Blood Products, and Reporting Changes to an Approved Application; Public Workshop   | 1            |
| D0477                | 0477              | 10/15/97                 | Revision of the Requirements for a Responsible Head for Biological Establishments; Final Rule   | 3            |
| D0475                | 0475              | 10/07/97                 | Expedited Safety Reporting Requirements for Human Drug and Biological Products; Final Rule  | 17           |
| D0469                | 0469              | 09/24/97                 | Investigational New Drug Applications; Proposed Amendment to Clinical Hold Regulations for Products Intended for Life-Threatening Diseases                          | 9            |
| D0468                | 0468              | 09/23/97                 | Biological Products; Reporting of Errors and Accidents in Manufacturing   | 7            |
| D0464                | 0464              | 09/08/97                 | Draft Guidance for Industry: Efficacy Evaluation of Hemoglobin-and Perfluorocarbon-Based Oxygen Carriers, Availability  | 2            |
| D0456                | 0456              | 08/27/97                 | Guidance for Industry: on Postmarketing Adverse Experience Reporting for Human Drug and Licensed Biological Products: Clarification of What to Report; Availability | 2            |
| D0458                | 0458              | 08/27/97                 | Specific Requirements on Content and Format of Labeling for Human Prescription Drugs; Addition of "Geriatric Use" Subsection in the Labeling; Final Rule            | 14           |
| D0452                | 0452              | 08/25/97                 | Draft Guidance for Industry: on Testing Limits in Stability Protocols for Standardized Grass Pollen Extracts; Availability  | 2            |
| D0454                | 0454              | 08/25/97                 | Biologics Regulations; Reporting Changes to an Approved Application; Open Public Meeting, 9/24/97   | 2            |

| <i>Hard<br/>Copy</i> | <i>FAX<br/>ID</i> | <i>Document<br/>Date</i> | <i>Title</i>   | <i>Pages</i> |
|----------------------|-------------------|--------------------------|--|--------------|
| D0448                | 0448              | 08/15/97                 | Regulations Requiring Manufacturers to Assess the Safety and Effectiveness of New Drugs and Biological Products in Pediatric Patients; Proposed Rule   | 18           |
| D0447                | 0447              | 08/12/97                 | Draft Guidance for Industry: Consumer-Directed Broadcast Advertisements; Availability  | 3            |
| D0441                | 0441              | 07/29/97                 | Human Tissue Intended for Transplantation; Final Rule  | 19           |
| D0442                | 0442              | 07/29/97                 | Guidance for Screening and Testing of Donors of Human Tissue Intended for Transplantation; Availability  | 2            |
| D0438                | 0438              | 07/24/97                 | Guidance for Industry: Changes To An Approved Application For Specified Biotechnology and Specified Synthetic Biological Products; Availability and Guidance for Industry: Changes To An Approved Application: Biological Products; Availability | 3            |
| D0439                | 0439              | 07/24/97                 | Changes to an Approved Application; Guidance for Industry: Changes to an Approved Application For Specified Biotechnology and Specified Synthetic Biological Products and Biological Products; Final Rule  | 15           |
| D0432                | 0432              | 07/15/97                 | Draft Guidance for Industry: Submission of Documentation in Drug Applications for Container Closure Systems Used for the Packaging of Human Drugs and Biologics; Availability  | 2            |
| D0427                | 0427              | 06/25/97                 | Postmarketing Expedited Adverse Experience Reporting for Human Drug and Licensed Biological Products; Increased Frequency Reports; Final Rule  | 3            |
| D0424                | 0424              | 06/18/97                 | Draft Guidance for Industry: Computerized Systems Used in Clinical Trials; Availability  | 1            |
| D0395                | 0395              | 04/14/97                 | Release of Establishment Inspection Report to the Inspected Establishment  | 1            |
| D0393                | 0393              | 04/10/97                 | Guidance for Industry: for the Evaluation of Combination Vaccines for Preventable Diseases: Production, Testing and Clinical Studies; Availability   | 2            |
| D0420                | 0420              | 03/20/97                 | Electronic Submissions; Establishment of Public Docket   | 1            |
| D0421                | 0421              | 03/20/97                 | Electronic Records; Electronic Signatures; Final Rule  | 38           |
| D0379                | 0379              | 03/05/97                 | Preclearance of Promotional Labeling; Clarification  | 1            |
| D0376                | 0376              | 03/04/97                 | Proposed Approach to Regulation of Cellular and Tissue-Based Products; Availability and Public Meeting   | 2            |

| <i>Hard<br/>Copy</i> | <i>FAX<br/>ID</i> | <i>Document<br/>Date</i> | <i>Title</i>   | <i>Pages</i> |
|----------------------|-------------------|--------------------------|--|--------------|
| D0371                | 0371              | 02/28/97                 | Points to Consider in the Manufacture and Testing of Monoclonal Antibody Products for Human Use (1997)   | 2            |
| D0388                | 0388              | 02/27/97                 | The Food and Drug Administration's Development, Issuance, and Use of Guidance Documents  | 12           |
| D0362                | 0362              | 01/29/97                 | Revision of the Requirements for a Responsible Head for Biological Establishments; Proposed rule   | 3            |
| D0340                | 0340              | 11/06/96                 | Prominence of Name of Distributor of Biological Products; Final Rule   | 3            |
| D0334                | 0334              | 10/23/96                 | Announcement of the Establishment of the Advisory Committee on Blood Safety and Availability and Request for Nominations for Members of the Committee; Notice  | 2            |
| D0331                | 0331              | 10/09/96                 | International Conference on the Virological Safety of Plasma Derivatives; Public Meeting; Notice   | 2            |
| D0322                | 0322              | 09/23/96                 | Draft Public Health Service Guideline on Infectious Disease Issues in Xenotransplantation; Notice  | 14           |
| D0319                | 0319              | 09/09/96                 | Current Good Manufacturing Practices for Blood and Blood Components: Notification of Consignees Receiving Blood and Blood Components at Increased Risk for Transmitting HIV Infection; Final Rule  | 11           |
| D0307                |                   | 06/24/96                 | Guidance for Industry: in Designing Clinical Programs for Developing Human Drugs, Medical Devices, or Biological Products Intended for the Treatment of Rheumatoid Arthritis; Availability of Draft Guidance; Notice of Public Workshop on Juvenile Rheumatoid Arthritis | 2            |
| D0303                | 0303              | 05/28/96                 | Guidance on Application for Products Comprised of Living Autologous Cells Manipulated Ex Vivo and Intended for Structural Repair or Reconstruction; Availability   | 2            |
| D0296                | 0296              | 05/14/96                 | Elimination of Establishment License Application for Specified Biotechnology and Specified Synthetic Biological Products; Final Rule   | 7            |
| D0293                | 0293              | 05/03/96                 | Current Good Manufacturing Practice; Proposed Amendment of Certain Requirements for Finished Pharmaceuticals; Proposed Rule  | 13           |
| D0292                |                   | 04/29/96                 | Gene Therapy Conference: Development and Evaluation of Phase 1 Products and Workshop on Vector Development; Notice of Public Conference  | 2            |
| D0290                |                   | 04/26/96                 | Guidance Concerning Demonstration of Comparability of Human Biological Products; Availability  | 2            |

| <i>Hard<br/>Copy</i> | <i>FAX<br/>ID</i> | <i>Document<br/>Date</i> | <i>Title</i>   | <i>Pages</i> |
|----------------------|-------------------|--------------------------|--|--------------|
| D0272                | 0272              | 01/29/96                 | 1) Well-Characterized Biotechnology Products; Elimination of Establishment License Application; 2) Changes to an Approved Application; 3) Draft Guidance; Changes to an Approved Application for Well-Characterized Therapeutic Recombinant DNA-Derived and Monoclonal Antibody Biotechnology Products; Availability | 18           |
| D0270                |                   | 01/24/96                 | Guidance for Industry: Content and Format of Investigational New Drug Applications (INDs) for Phase 1 Studies of Drugs, Including Well Characterized, Therapeutic, Biotechnology-Derived Products; Availability  | 2            |
| D0263                | 0263              | 01/03/96                 | Statement of Organization, Functions, and Delegations of Authority   | 2            |
| D0256                | 0256              | 12/08/95                 | Interim Definition and Elimination of Lot-by-Lot Release for Well-Characterized Therapeutic Recombinant DNA-Derived and Monoclonal Antibody Biotechnology Products   | 6            |
| D0224                |                   | 07/18/95                 | Public Hearing: Products Comprised of Living Autologous Cells Manipulated Ex Vivo and Intended for Implantation for Structural Repair or Reconstruction  | 4            |
| D0200                | 0200              | 02/23/95                 | Home Specimen Collection Kit Systems Intended for Human Immunodeficiency Virus (HIV-1 and/or HIV-2) Antibody Testing; Revisions to Previous Guidance   | 2            |
| D0189                |                   | 12/13/94                 | Specific Requirements on Content and Format of Labeling for Human Prescription Drugs; Revision of "Pediatric Use" Subsection in the Labeling; Final Rule   | 14           |
| D0185                | 0185              | 11/16/94                 | Biological Products; Allergenic Extracts Classified in Category IIIB; Final Order; Revocation of Licenses  | 10           |
| D0180                | 0180              | 10/27/94                 | Adverse Experience Reporting Requirements for Human Drug and Licensed Biological Products; Proposed Rule   | 20           |
| D0181                | 0181              | 10/27/94                 | Adverse Experience Reporting Requirements for Licensed Biological Products; Final Rule   | 12           |
| D0152                | 0152              | 12/14/93                 | Human Tissue Intended for Transplantation; Interim Rule; Opportunity for Public Comment  | 9            |
| D0149                | 0149              | 10/14/93                 | FR: Application of Current Statutory Authorities to Human Somatic Cell Therapy Products and Gene Therapy Products; Notice  | 5            |
| D0140                | 0140              | 07/20/93                 | FR: Alternatives to Lot Release  | 3            |

| <i>Hard<br/>Copy</i>  | <i>FAX<br/>ID</i> | <i>Document<br/>Date</i> | <i>Title</i>   | <i>Pages</i> |
|-----------------------|-------------------|--------------------------|--|--------------|
| D0042                 |                   | 11/21/83                 | Interstate Shipment of Interferon for Investigational Use in Laboratory Research Animals or Tests in Vitro   | 2            |
| <i><u>General</u></i> |                   |                          |  |              |
| D0259                 | 0259              | 02/01/01                 | CBER Organizational Chart  | 25           |
| D0260                 | 0260              | 02/01/01                 | CBER Organizational Listing  | 15           |
| D0632                 | 0632              | 10/01/00                 | CBER Organizational Chart Overview   | 1            |
| D0283                 | 0283              | 07/28/00                 | CBER Telephone and Mail Routing Directory  | 22           |
| D0021                 | 0021              | 09/29/99                 | FDA Licensed / Approved HIV, HTLV and Hepatitis Tests  | 5            |
| D0019                 | 0019              | 04/13/99                 | Information on Submitting an IND Application for a Biological Product  | 8            |
| D0681                 |                   | 03/05/99                 | Anthrax Information Packet   | 37           |
| D0407                 | 0407              | 08/05/98                 | Notification Process for Transfusion Related Fatalities and Donation Related Deaths (revised telephone number)                                       | 1            |
| D0576                 | 0576              | 05/20/98                 | List of Drugs for Which Additional Pediatric Information May Produce Health Benefits in the Pediatric Population                                     | 25           |
| D0525                 | 0525              | 01/14/98                 | Proposal by Council on Radionuclides and Radiopharmaceuticals for a Regulation Governing Evaluation and Approval of Diagnostic Radiopharmaceuticals  | 7            |
| D0504                 | 0504              | 11/12/97                 | PDUFA Reauthorization Performance Goals and Procedures   | 12           |
| D0330                 | 0330              | 10/15/97                 | Submission Requirements for Requesting Certificates for Exporting Products to Foreign Countries  | 7            |
| D0451                 | 0451              | 07/30/97                 | Team Biologics - A Plan for Reinventing FDA's Ability to Optimize Compliance of Regulated Biologics Industries                                       | 14           |
| D0188                 | 0188              | 06/01/97                 | Guide to Inspections of Source Plasma Establishments (Division of Field Investigations, Office of Regional Operations, Office of Regulatory Affairs) | 20           |
| D0425                 | 0425              | 05/19/97                 | Application to Market a New Drug, Biologic, or an Antibiotic Drug for Human Use, Form 356h, 4/97   | 5            |
| D0394                 | 0394              | 03/28/97                 | FDA Backgrounder - A Handbook for Requesting Information and Records from FDA  | 3            |

| <i>Hard<br/>Copy</i> | <i>FAX<br/>ID</i> | <i>Document<br/>Date</i> | <i>Title</i>  | <i>Pages</i> |
|----------------------|-------------------|--------------------------|---|--------------|
| D0378                | 0378              | 03/04/97                 | HHS News - Reinventing the Regulation of Human Tissue   | 5            |
| D0508                | 0508              | 03/01/97                 | Transmittal of Advertisements and Promotional Labeling for Drugs and Biologics for Human Use - 2253 Form                                | 2            |
| D0373                | 0373              | 02/28/97                 | Reinventing the Regulation of Human Tissue-Feb 1997   | 18           |
| D0326                | 0326              | 10/03/96                 | MedWatch Form (6/93)  | 2            |
| D0288                |                   | 04/19/96                 | Public Meeting - Changes to Approved Application - Proposed Rule and Draft Guidance   | 41           |
| D0281                | 0281              | 03/01/96                 | Reinventing the Regulation of Cancer Drugs - Accelerating Approval and Expanding Access; President Bill Clinton, Vice President Al Gore | 9            |
| D0251                |                   | 12/01/95                 | Establishments & Products Book  | 178          |
| D0247                | 0247              | 11/01/95                 | Reinventing the Regulation of Drugs Made from Biotechnology; President Bill Clinton, Vice President Al Gore                             | 12           |
| D0232                | 0232              | 08/14/95                 | CBER Mission and Vision Statements  | 2            |
| D0233                | 0233              | 08/14/95                 | CBER Strategic Plan for 2004  | 23           |
| D0227                | 0227              | 08/01/95                 | Blood Registration Information and Form 2830  | 3            |
| D0195                | 0195              | 01/30/95                 | Review Checklists from FDA/CBER Workshop for Licensing Blood Establishments   | 27           |
| D0174                | 0174              | 09/01/94                 | Guide to Inspections of Blood Banks, Division of Field Investigations, Office of Regional Operations, Office of Regulatory Affairs      | 18           |
| D0166                | 0166              | 06/01/94                 | FDA Backgrounder: How to Make a Freedom of Information Act Request to FDA   | 3            |
| D0163                | 0163              | 05/01/94                 | Application for Establishment License for Manufacture of Biological Products, FDA Form 3210   | 18           |
| D0158                | 0158              | 01/13/94                 | FDA Advisory Committees Information Line Instructions   | 1            |
| D0148                | 0148              | 10/01/93                 | Methods of the Allergenic Products Testing Laboratory   | 120          |
| D0122                |                   | 03/01/92                 | Recommended Methods for Evaluating Potency, Specificity and Reactivity of Anti-Human Globulin   | 33           |
| D0123                |                   | 03/01/92                 | Recommended Methods for Blood Grouping Reagents Evaluation  | 60           |
| D0120                |                   | 12/31/91                 | National Vaccine Injury Compensation Program  | 38           |

| <i>Hard<br/>Copy</i>   | <i>FAX<br/>ID</i> | <i>Document<br/>Date</i> | <i>Title</i>  | <i>Pages</i> |
|------------------------|-------------------|--------------------------|---|--------------|
| D0118                  |                   | 11/25/91                 | Memo: Draft Document on Clinical End Points for Monoclonal Imaging Agents   | 3            |
| D0101                  |                   | 03/01/90                 | From Test Tube to Patient: New Drug Development in the United States  | 59           |
| D0091                  |                   | 08/23/89                 | Information Relevant to the Manufacture of Acellular Pertussis Vaccine  | 1            |
| D0078                  |                   | 10/01/88                 | National Vaccine Injury Compensation Program  | 17           |
| D0055                  |                   | 11/01/85                 | Recommended Methods for Short Ragweed Pollen Extracts   | 3            |
| D0012                  |                   |                          | Technology Transfer Act of 1986; CRADA, and MTA Packet  | 77           |
| D0016                  |                   |                          | Summary of the Approval Process for a Biological Product  | 2            |
| D0017                  |                   |                          | How To Obtain FDA Regulations   | 1            |
| D0018                  |                   |                          | Public Health Service Act (Biological Products), Sections 351 and 352   | 6            |
| D0022                  |                   |                          | Intercenter Agreement Between the Center for Biologics Evaluation and Research and the Center for Devices and Radiological Health | 2            |
| D0023                  |                   |                          | Intercenter Agreement Between the Center for Drug Evaluation and Research and Center for Biologics Evaluation and Research        | 16           |
| D0024                  |                   |                          | Intercenter Agreement Between the Center for Drug Evaluation and Research and the Center for Devices and Radiological Health      | 14           |
| D0025                  |                   |                          | Medwatch, the FDA Medical Products Reporting Program  | 38           |
| <i><u>Guidance</u></i> |                   |                          |   |              |
| D0958                  | 0958              | 05/25/01                 | Guidance for Industry: IND Meetings for Human Drugs and Biologics; Chemistry, Manufacturing and Controls Information              | 13           |
| D0956                  | 0956              | 05/11/01                 | Guidance for Industry: E10 Choice of Control Group and Related Issues in Clinical Trials  | 37           |
| D0954                  | 0954              | 05/03/01                 | Guidance for Industry: Providing Regulatory Submissions in Electronic Format - Postmarketing Expedited Safety Reports             | 12           |

| <i>Hard<br/>Copy</i> | <i>FAX<br/>ID</i> | <i>Document<br/>Date</i> | <i>Title</i>   | <i>Pages</i> |
|----------------------|-------------------|--------------------------|--|--------------|
| D0951                | 0951              | 04/20/01                 | Draft Guidance for Industry: Using FDA-Approved Patient Labeling in Consumer-Directed Print Advertisements   | 7            |
| D0946                | 0946              | 04/04/01                 | Draft Guidance for Industry; Reports on the Status of Postmarketing Studies - Implementation of Section 130 of the Food and Drug Administration Modernization Act of 1997  | 24           |
| D0943                | 0943              | 03/29/01                 | Guidance for Industry: Monoclonal Antibodies Used as Reagents in Drug Manufacturing  | 11           |
| D0938                | 0938              | 03/13/01                 | Guidance for Industry: Acceptance of Foreign Clinical Studies  | 4            |
| D0937                | 0937              | 03/12/01                 | Draft Guidance for Industry: Postmarketing Safety Reporting for Human Drug and Biological Products Including Vaccines  | 50           |
| D0935                | 0935              | 02/15/01                 | Draft Guidance for Industry; Disclosing Information in Connection with Open Advisory Committee Meetings Related to the Testing or Approval of Biologic Products and Convened by the Center for Biologics Evaluation and Research | 13           |
| D0932                | 0932              | 02/07/01                 | Draft Guidance for Industry: Source Animal, Product, Preclinical, and Clinical Issues Concerning the Use of Xenotransplantation Products in Humans   | 61           |
| D0930                | 0930              | 01/31/01                 | Draft Guidance for Industry: Providing Regulatory Submissions in Electronic Format - Prescription Drug Advertising and Promotional Labeling  | 8            |
| D0929                | 0929              | 01/30/01                 | Guidance for Industry: Recommendations for Collecting Red Blood Cells by Automated Apheresis Methods   | 11           |
| D0928                | 0928              | 01/23/01                 | DRAFT Guidance for Industry; Pre-Storage Leukocyte Reduction of Whole Blood and Blood Components Intended for Transfusion  | 24           |
| D0915                | 0915              | 12/04/00                 | Draft Guidance for Industry on Recommendations for Complying With the Pediatric Rule (21 CFR 314.55(a) and 601.27(a))  | 19           |
| D0912                | 0912              | 11/22/00                 | Guidance for Industry: Use of Sterile Connecting Devices in Blood Bank Practices   | 10           |
| D0909                | 0909              | 11/20/00                 | Guidance for Reviewers: Potency Limits for Standardized Dust Mite and Grass Allergen Vaccines: A Revised Protocol  | 15           |
| D0910                | 0910              | 11/20/00                 | Guidance for Industry: Testing Limits in Stability Protocols for Standardized Grass Pollen Extracts  | 10           |

| <i>Hard Copy</i> | <i>FAX ID</i> | <i>Document Date</i> | <i>Title</i>   | <i>Pages</i> |
|------------------|---------------|----------------------|--|--------------|
| D0906            | 0906          | 11/09/00             | Draft Guidance for Industry on Cancer Drug and Biological Products - Clinical Data in Marketing Applications   | 13           |
| D0895            | 0895          | 10/18/00             | Guidance for Industry: Supplemental Guidance on Testing for Replication Competent Retrovirus in Retroviral Vector Based Gene Therapy Products and During Follow-up of Patients in Clinical Trials Using Retroviral Vectors | 15           |
| D0898            | 0898          | 10/18/00             | Draft Guidance: PHS Guideline on Infectious Disease Issues in Xenotransplantation  | 58           |
| D0890            | 0890          | 10/04/00             | Guidance for Industry Q & A: Content and Format of INDs for Phase 1 Studies of Drugs, Including Well-Characterized, Therapeutic, Biotechnology-Derived Products  | 4            |
| D0882            | 0882          | 08/31/00             | Draft Guidance for Industry: Considerations for Reproductive Toxicity Studies for Preventive Vaccines for Infectious Disease Indications   | 10           |
| D0865            | 0865          | 07/31/00             | Draft Guidance for Industry: Developing Medical Imaging Drugs and Biological Products  | 63           |
| D0859            | 0859          | 07/18/00             | Draft Guidance: CBER Pilot Licensing Program for Immunization of Source Plasma Donors Using Immunogen Red Blood Cells Obtained from an Outside Supplier  | 14           |
| D0856            | 0856          | 06/28/00             | Draft Guidance for Industry: Chronic Cutaneous Ulcer and Burn Wounds - Developing Products for Treatment   | 22           |
| D0851            | 0851          | 06/23/00             | Guidance for Industry: Availability of Licensed Donor Screening Tests Labeled for Use with Cadaveric Blood Specimens   | 4            |
| D0849            | 0849          | 06/21/00             | Draft Guidance for Industry: Pediatric Oncology Studies in Response to a Written Request   | 8            |
| D0847            | 0847          | 06/17/00             | Draft Guidance for Industry on the Content and Format of the Adverse Reactions Section of Labeling for Human Prescription Drugs and Biologics  | 14           |
| D0843            | 0843          | 06/08/00             | Draft Guidance for Industry: Recommendations for Donor Questioning Regarding Possible Exposure to Malaria  | 7            |
| D0839            | 0839          | 06/06/00             | Guidance for Industry: Recognition and Use of a Standard for the Uniform Labeling of Blood and Blood Components  | 5            |
| D0826            | 0826          | 03/29/00             | Draft Guidance for Industry: Information Program on Clinical Trials for Serious or Life-Threatening Diseases: Establishment of a Data Bank   | 9            |

| <i>Hard<br/>Copy</i> | <i>FAX<br/>ID</i> | <i>Document<br/>Date</i> | <i>Title</i>   | <i>Pages</i> |
|----------------------|-------------------|--------------------------|--|--------------|
| D0822                | 0822              | 03/15/00                 | Guidance for Industry: Gamma Irradiation of Blood and Blood Components: A Pilot Program for Licensing  | 14           |
| D0813                | 0813              | 02/28/00                 | Guidance for Industry: Formal Meetings With Sponsors and Applicants for PDUFA Products   | 12           |
| D0815                | 0815              | 02/28/00                 | Guidance for Industry: Formal Dispute Resolution Appeals Above the Division Level  | 10           |
| D0800                | 0800              | 02/04/00                 | Draft Guidance for Industry: IND Meetings for Human Drugs and Biologics; Chemistry, Manufacturing and Controls Information   | 14           |
| D0796                | 0796              | 01/03/00                 | Draft Guidance for Industry: Changes to an Approved Application: Biological Products: Human Blood and Blood Components Intended for Transfusion or for Further Manufacture   | 27           |
| D0801                | 0801              | 01/01/00                 | Draft Guidance for Reviewers: Potency Limits for Standardized Dust Mite and Grass Allergen Vaccines: A Revised Protocol  | 16           |
| D0792                | 0792              | 12/23/99                 | Draft Guidance for Industry: Precautionary Measures to Reduce the Possible Risk of Transmission of Zoonoses by Blood and Blood Products from Xenotransplantation Product Recipients and Their Contacts             | 11           |
| D0789                | 0789              | 12/14/99                 | Guidance for Industry: In the Manufacture and Clinical Evaluation of In Vitro Tests to Detect Nucleic Acid Sequences of Human Immunodeficiency Viruses Types 1 and 2   | 24           |
| D0787                | 0787              | 12/07/99                 | Draft Guidance for Industry: Pharmacokinetics in Patients With Impaired Hepatic Function: Study Design, Data Analysis and Impact on Dosing and Labeling  | 20           |
| D0804                | 0804              | 12/01/99                 | Draft Guidance for Industry: Special Protocol Assessment   | 12           |
| D0784                | 0784              | 11/26/99                 | Draft Guidance for Industry: Application of Current Statutory Authority to Nucleic Acid Testing of Pooled Plasma   | 8            |
| D0783                | 0783              | 11/24/99                 | Guidance for Industry: In Vivo Drug Metabolism / Drug Interaction Studies - Study Design, Data Analysis, and Recommendations for Dosing and Labeling   | 18           |
| D0781                | 0781              | 11/23/99                 | Guidance for Industry: Revised Precautionary Measures to Reduce the Possible Risk of Transmission of Creutzfeldt-Jakob Disease (CJD) and New Variant Creutzfeldt-Jakob Disease (nvCJD) by Blood and Blood Products | 16           |

| <i>Hard<br/>Copy</i> | <i>FAX<br/>ID</i> | <i>Document<br/>Date</i> | <i>Title</i>   | <i>Pages</i> |
|----------------------|-------------------|--------------------------|--|--------------|
| D0777                | 0777              | 11/22/99                 | REVISED Guidance for Industry: Providing Regulatory Submissions to the Center for Biologics Evaluation and Research (CBER) in Electronic Format-Biologics Marketing Applications [Biologics License Application (BLA), Product License Application (PLA)/ Establishment License Application (ELA) and New Drug Applications (NDA)] | 65           |
| D0771                | 0771              | 11/03/99                 | Draft Guidance for Industry: Supplemental Guidance on Testing for Replication Competent Retrovirus in Retroviral Vector Based Gene Therapy Products & During Follow-up of Patients in Clinical Trials Using Retroviral Vectors   | 16           |
| D0840                |                   | 11/01/99                 | Guidance for Industry: United States Industry Consensus Standard for the Uniform Labeling of Blood and Blood Components Using ISBT 128 - AVAILABLE IN HARD COPY ONLY - CALL 1-800-835-4709 OR 1-301-827-2000   | 95           |
| D0764                | 0764              | 10/08/99                 | Guidance for Industry: Qualifying for Pediatric Exclusivity Under Section 505A of the Federal Food, Drug and Cosmetic Act  | 25           |
| D0756                | 0756              | 09/13/99                 | Guidance for Industry: Submission of Abbreviated Reports and Synopses in Support of Marketing Applications   | 14           |
| D0755                | 0755              | 09/01/99                 | Guidance for Industry: Revised Recommendations for the Invalidation of Test Results When Using Licensed and 510(k) Cleared Bloodborne Pathogen Assays to Test Donors   | 9            |
| D0753                | 0753              | 08/27/99                 | Guidance for Industry: Possible Dioxin / PCB Contamination of Drug and Biological Products   | 4            |
| D0739                | 0739              | 08/17/99                 | Guidance for Industry: Revised Precautionary Measures to Reduce the Possible Risk of Transmission of Creutzfeldt-Jakob Disease (CJD) and New Variant Creutzfeldt-Jakob Disease (nvCJD) by Blood and Blood Products   | 17           |
| D0742                | 0742              | 08/17/99                 | Draft Guidance for Industry: Information Request and Discipline Review Letters Under the Prescription Drug User Fee Act  | 8            |
| D0738                | 0738              | 08/06/99                 | Guidance for Industry: Consumer- Directed Broadcast Advertisements   | 6            |
| D0734                | 0734              | 08/03/99                 | Draft Guidance for Industry: Cooperative Manufacturing Arrangements for Licensed Biologics   | 13           |
| D0732                | 0732              | 07/26/99                 | Draft Guidance for Industry: Interpreting Sameness of Monoclonal Antibody Products Under the Orphan Drug Regulations   | 7            |

| <i>Hard<br/>Copy</i> | <i>FAX<br/>ID</i> | <i>Document<br/>Date</i> | <i>Title</i>  | <i>Pages</i> |
|----------------------|-------------------|--------------------------|---|--------------|
| D0729                | 0729              | 07/15/99                 | Draft Guidance for Industry: Clinical Development Programs for Drugs, Devices, and Biological Products Intended for the Treatment of Osteoarthritis (OA)  | 12           |
| D0726                | 0726              | 07/07/99                 | Guidance for Industry: Container Closure Systems for Packaging Human Drugs and Biologics; Chemistry, Manufacturing, and Controls Documentation  | 56           |
| D0721                | 0721              | 06/24/99                 | Draft Guidance for Industry: Monoclonal Antibodies Used as Reagents in Drug Manufacturing; Availability   | 17           |
| D0717                | 0717              | 06/17/99                 | Draft Guidance for Industry: Current Good Manufacturing Practice for Blood and Blood Components: (1) Quarantine and Disposition of Prior Collections from Donors with Repeatedly Reactive Screening Tests for Hepatitis C Virus (HCV); (2) Supplemental Testing | 28           |
| D0712                | 0712              | 06/04/99                 | Draft Guidance for Industry: Establishing Pregnancy Registries  | 26           |
| D0713                | 0713              | 06/04/99                 | Draft Reviewer Guidance: Evaluation of Human Pregnancy Outcome Data   | 34           |
| D0708                | 0708              | 05/20/99                 | Guidance for Industry: Efficacy Studies to Support Marketing of Fibrin Sealant Products Manufactured for Commercial Use   | 5            |
| D0709                | 0709              | 05/20/99                 | Draft Guidance for Industry: For Platelet Testing and Evaluation of Platelet Substitute Products  | 9            |
| D0705                | 0705              | 05/10/99                 | Guidance for Industry: for the Submission of Chemistry, Manufacturing and Controls and Establishment Description Information for Human Blood and Blood Components Intended for Transfusion or for Further Manufacture and For the Completion of the Form FDA 3  | 33           |
| D0699                | 0699              | 04/23/99                 | Guidance for Industry: On the Content and Format of Chemistry, Manufacturing and Controls Information and Establishment Description Information for an Allergenic Extract or Allergen Patch Test  | 27           |
| D0696                | 0696              | 04/20/99                 | Draft Guidance for Industry: INDs for Phase 2 and 3 Studies of Drugs, Including Specified Therapeutic Biotechnology-Derived Products; Chemistry, Manufacturing and Controls Content and Format  | 18           |
| D0693                | 0693              | 04/06/99                 | Guidance for Industry: Public Health Issues Posed by the Use of Nonhuman Primate Xenografts in Humans   | 9            |
| D0690                | 0690              | 03/26/99                 | Draft Guidance for Industry: Accelerated Approval Products - Submission of Promotional Materials  | 7            |

| <i>Hard<br/>Copy</i> | <i>FAX<br/>ID</i> | <i>Document<br/>Date</i> | <i>Title</i>   | <i>Pages</i> |
|----------------------|-------------------|--------------------------|--|--------------|
| D0687                | 0687              | 03/19/99                 | Draft Guidance for Industry: Formal Dispute Resolution: Appeals Above the Division Level   | 12           |
| D0688                | 0688              | 03/19/99                 | Draft Guidance for Industry: Formal Meetings With Sponsors and Applicants for PDUFA Products   | 12           |
| D0686                | 0686              | 03/12/99                 | Draft Guidance for Industry: Product Name Placement, Size and Prominence in Advertising and Promotional Labeling   | 7            |
| D0683                | 0683              | 03/08/99                 | Guidance for Industry: Content and Format of Chemistry, Manufacturing and Controls Information and Establishment Description Information for a Biological In Vitro Diagnostic Product                              | 22           |
| D0676                | 0676              | 02/17/99                 | Guidance for Industry: For the Submission of Chemistry, Manufacturing and Controls and Establishment Description Information for Human Plasma-Derived Biological Products, Animal Plasma or Serum-Derived Products | 19           |
| D0678                | 0678              | 02/17/99                 | Guidance for Industry: Clinical Development Programs for Drugs, Devices, and Biological Products for the Treatment of Rheumatoid Arthritis (RA)  | 50           |
| D0677                | 0677              | 02/10/99                 | Guidance for Industry: Population Pharmacokinetics   | 35           |
| D0672                | 0672              | 02/03/99                 | Guidance for Industry: FDA Approval of New Cancer Treatment Uses for Marketed Drug and Biological Products   | 13           |
| D0669                | 0669              | 01/28/99                 | Guidance for Industry: Providing Regulatory Submissions in Electronic Format - General Considerations  | 18           |
| D0666                | 0666              | 01/26/99                 | Guidance on Amended Procedures for Advisory Panel Meetings   | 5            |
| D0667                | 0667              | 01/21/99                 | Draft Guidance for Industry: Content and Format for Geriatric Labeling   | 13           |
| D0589                | 0589              | 01/06/99                 | Quarterly List of Guidance Documents at the Food and Drug Administration   | 16           |
| D0663                | 0663              | 01/05/99                 | Guidance for Industry: Content and Format of Chemistry, Manufacturing and Controls Information and Establishment Description Information for a Vaccine or Related Product  | 34           |
| D0653                | 0653              | 12/08/98                 | Draft Guidance for Industry: Gamma Radiation of Blood and Blood Components: A Pilot Program for Licensing  | 14           |

| <i>Hard<br/>Copy</i> | <i>FAX<br/>ID</i> | <i>Document<br/>Date</i> | <i>Title</i>   | <i>Pages</i> |
|----------------------|-------------------|--------------------------|--|--------------|
| D0652                | 0652              | 12/01/98                 | Draft Guidance for Industry: General Considerations for Pediatric Pharmacokinetic Studies for Drugs and Biological Products  | 12           |
| D0651                | 0651              | 11/27/98                 | United States Industry Consensus Standard for the Uniform Labeling of Blood and Blood Components Using ISBT 128  | 94           |
| D0644                | 0644              | 11/19/98                 | Draft Guidance for Industry: In Vivo Metabolism / Drug Interaction Studies - Study Design, Data Analysis and Recommendations for Dosing and Labeling   | 18           |
| D0642                | 0642              | 11/18/98                 | Guidance for Industry: Fast Track Drug Development Programs - Designation, Development and Application Review  | 62           |
| D0638                | 0638              | 10/30/98                 | Guidance for Industry: on Advisory Committees: Implementing Section 120 of the Food and Drug Administration Modernization Act of 1997  | 9            |
| D0631                | 0631              | 10/14/98                 | Draft Guidance for Industry: Developing Medical Imaging Drugs and Biologics  | 46           |
| D0628                | 0628              | 10/02/98                 | Guidance for Industry: Submitting Debarment Certification Statements   | 13           |
| D0621                | 0621              | 09/23/98                 | Guidance for Industry: Current Good Manufacturing Practice for Blood and Blood Components: (1) Quarantine and Disposition of Units from Prior Collections from Donors with Repeatedly Reactive Screening Tests for Antibody to Hepatitis C Virus (Anti-HCV); | 17           |
| D0616                | 0616              | 09/08/98                 | Guidance for Industry: How to Complete the Vaccine Adverse Event Reporting System Form (VAERS-1)   | 19           |
| D0596                | 0596              | 07/27/98                 | Guidance for Industry: Environmental Assessment of Human Drug and Biologics Applications   | 41           |
| D0597                | 0597              | 07/27/98                 | Draft Guidance for Industry: Recommendations for Collecting Red Blood Cells by Automated Apheresis Methods   | 6            |
| D0538                | 0538              | 07/21/98                 | Guidance for Industry: Implementation of Section 126 of the Food and Drug Administration Modernization Act of 1997- Elimination of Certain Labeling Requirements   | 6            |
| D0591                | 0591              | 07/10/98                 | Draft Guidance for Industry: In the Manufacture and Clinical Evaluation of In Vitro Tests to Detect Nucleic Acid Sequences of Human Immunodeficiency Virus Type 1  | 17           |

| <i>Hard<br/>Copy</i> | <i>FAX<br/>ID</i> | <i>Document<br/>Date</i> | <i>Title</i>  | <i>Pages</i> |
|----------------------|-------------------|--------------------------|---|--------------|
| D0588                | 0588              | 06/29/98                 | Guidance for Industry: Qualifying for Pediatric Exclusivity Under Section 505A of the Federal Food, Drug and Cosmetic Act   | 19           |
| D0585                | 0585              | 06/12/98                 | Draft Guidance for Industry: Exports and Imports Under the Export Reform and Enhancement Act of 1996  | 16           |
| D0584                | 0584              | 06/11/98                 | Guidance for Industry: Errors and Accidents Regarding Saline Dilution of Samples Used for Viral Marker Testing  | 3            |
| D0581                |                   | 06/08/98                 | Draft Guidance for Industry: Stability Testing of Drug Substances and Drug Products   | 114          |
| D0569                | 0569              | 05/15/98                 | Guidance for Industry: Providing Clinical Evidence of Effectiveness for Human Drugs and Biological Products   | 22           |
| D0570                | 0570              | 05/15/98                 | Guidance for Industry: Standards for the Prompt Review of Efficacy Supplements, Including Priority Efficacy Supplements   | 4            |
| D0571                | 0571              | 05/15/98                 | Guidance for Industry: Pharmacokinetics in Patients with Impaired Renal Function - Study Design, Data Analysis and Impact on Dosing and Labeling  | 17           |
| D0565                | 0565              | 05/14/98                 | Guidance for Industry: Classifying Resubmissions in Response to Action Letters  | 4            |
| D0567                | 0567              | 05/14/98                 | Guidance for Industry: Submitting and Reviewing Complete Responses to Clinical Holds  | 4            |
| D0560                | 0560              | 05/13/98                 | Draft Guidance for Industry: Pilot Program for Electronic Investigational New Drug (eIND) Applications for Biological Products  | 29           |
| D0561                | 0561              | 05/13/98                 | Draft Guidance for Industry: Electronic Submissions of a Biologics License Application (BLA) or Product License Application (PLA) / Establishment License Application (ELA) to the Center for Biologics Evaluation and Research | 47           |
| D0562                | 0562              | 05/13/98                 | Draft Guidance for Industry: Electronic Submissions of Case Report Forms (CRFs), Case Report Tabulations (CRTs) and Data to the Center for Biologics Evaluation and Research  | 35           |
| D0563                | 0563              | 05/13/98                 | Draft Guidance for Industry: Instructions for Submitting Electronic Lot Release Protocols to the Center for Biologics Evaluation and Research   | 8            |
| D0552                | 0552              | 04/17/98                 | Draft Guidance for Industry: Manufacturing, Processing or Holding Active Pharmaceutical Ingredients   | 57           |

| <i>Hard<br/>Copy</i> | <i>FAX<br/>ID</i> | <i>Document<br/>Date</i> | <i>Title</i>  | <i>Pages</i> |
|----------------------|-------------------|--------------------------|---|--------------|
| D0547                | 0547              | 03/30/98                 | Guidance for Industry: Guidance for Human Somatic Cell Therapy and Gene Therapy   | 30           |
| D0544                | 0544              | 03/20/98                 | Guidance for Industry: Supplemental Testing and the Notification of Consignees of Donor Test Results for Antibody to Hepatitis C Virus (Anti-HCV)   | 8            |
| D0530                | 0530              | 02/12/98                 | Draft Guidance for Industry: Clinical Development of Programs for Drugs, Devices and Biological Products Intended for Treatment of Osteoarthritis (OA)  | 8            |
| D0520                | 0520              | 01/28/98                 | Draft Guidance for Industry: Container and Closure Integrity Testing in Lieu of Sterility Testing as a Component of the Stability Protocol for Sterile Products   | 8            |
| D0507                | 0507              | 01/08/98                 | Guidance for Industry: Year 2000 Date Change for Computer Systems and Software Applications Used in the Manufacture of Blood Products   | 6            |
| D0510                | 0510              | 01/05/98                 | Draft Guidance for Industry: Promoting Medical Products in a Changing Healthcare Environment; I. Medical Product Promotion by Healthcare Organizations or Pharmacy Benefits Management Companies (PBMS) | 6            |
| D0473                | 0473              | 10/07/97                 | Guidance for Industry: The Sourcing and Processing of Gelatin to Reduce the Potential Risk Posed by Bovine Spongiform Encephalopathy (BSE) in FDA-Regulated Products for Human Use                      | 15           |
| D0463                | 0463              | 09/01/97                 | Guidance for Industry: Efficacy Evaluation of Hemoglobin-and Perfluorocarbon-Based Oxygen Carriers  | 6            |
| D0457                | 0457              | 08/27/97                 | Guidance for Industry: Postmarketing Adverse Experience Reporting for Human Drug and Licensed Biological Products: Clarification of What to Report  | 7            |
| D0453                | 0453              | 08/25/97                 | Guidance for Industry: on Testing Limits in Stability Protocols for Standardized Grass Pollen Extracts  | 10           |
| D0449                | 0449              | 08/15/97                 | Guidance for Industry: Donor Screening for Antibodies to HTLV-II  | 9            |
| D0440                | 0440              | 07/29/97                 | Guidance for Industry: Screening and Testing of Donors of Human Tissue Intended for Transplantation   | 13           |
| D0436                | 0436              | 07/24/97                 | Guidance for Industry: Changes to an Approved Application: Biological Products  | 13           |
| D0437                | 0437              | 07/24/97                 | Guidance for Industry: Changes to an Approved Application for Specified Biotechnology and Specified Synthetic Biological Products   | 10           |

| <i>Hard<br/>Copy</i> | <i>FAX<br/>ID</i> | <i>Document<br/>Date</i> | <i>Title</i>   | <i>Pages</i> |
|----------------------|-------------------|--------------------------|--|--------------|
| D0392                | 0392              | 04/10/97                 | Guidance for Industry: for the Evaluation of Combination Vaccines for Preventable Diseases: Production, Testing and Clinical Studies   | 24           |
| D0377                | 0377              | 03/04/97                 | Tables 1 and 2 from Proposed Approach to Regulation of Cellular and Tissue-Based Products  | 6            |
| D0374                | 0374              | 02/28/97                 | Proposed Approach to Regulation of Cellular and Tissue-Based Products  | 32           |
| D0358                | 0358              | 01/10/97                 | Guidance for Industry: for the Submission of Chemistry, Manufacturing, and Controls Information and Establishment Description for Autologous Somatic Cell Therapy Products                         | 22           |
| D0338                | 0338              | 11/04/96                 | Draft Guidance for Industry: Submitting Application Archival Copies in Electronic Format   | 7            |
| D0339                | 0339              | 11/04/96                 | Draft Guidance for Industry: Electronic Submission of Case Report Forms and Case Report Tabulations  | 12           |
| D0342                | 0342              | 09/20/96                 | Draft Guidance for Industry: Manufacture, Processing or Holding of Active Pharmaceutical Ingredients   | 63           |
| D0314                | 0314              | 08/15/96                 | Guidance for Industry: for the Submission of Chemistry, Manufacturing, and Controls Information for a Therapeutic Recombinant DNA-Derived Product or a Monoclonal Antibody Product for In Vivo Use | 27           |
| D0302                | 0302              | 05/24/96                 | Guidance on Applications for Products Comprised of Living Autologous Cells Manipulated Ex Vivo and Intended for Structural Repair of Reconstruction  | 10           |
| D0301                | 0301              | 05/23/96                 | Guidance for Industry: The Content and Format for Pediatric Use Supplements  | 7            |
| D0291                | 0291              | 04/26/96                 | FDA Guidance Concerning Demonstration of Comparability of Human Biological Products, Including Therapeutic Biotechnology-Derived Products  | 10           |
| D0280                | 0280              | 03/01/96                 | Computer Assisted Product License Application (CAPLA) Guidance Manual  | 87           |
| D0246                | 0246              | 11/01/95                 | Content and Format of Investigational New Drug Applications (INDs) for Phase 1 Studies of Drugs, Including Well-Characterized, Therapeutic, Biotechnology-derived Products                         | 17           |
| D0223                | 0223              | 07/11/95                 | Guideline for Quality Assurance in Blood Establishments  | 37           |
| D0512                | 0512              | 11/01/94                 | Guidance for Industry: for the Submission of Chemistry, Manufacturing, and Controls Information for Synthetic Peptide Substances   | 16           |

| <i>Hard<br/>Copy</i>               | <i>FAX<br/>ID</i> | <i>Document<br/>Date</i> | <i>Title</i>   | <i>Pages</i> |
|------------------------------------|-------------------|--------------------------|--|--------------|
| D0182                              | 0182              | 10/27/94                 | Guidance on Alternatives to Lot Release for Licensed Biological Products   | 6            |
| D0171                              | 0171              | 08/01/94                 | OELPS, Advertising and Promotional Labeling Staff Procedural Guidance Document (Draft)   | 6            |
| D0138                              | 0138              | 07/12/93                 | CBER Refusal to File (RTF) Guidance for Product and Establishment License Applications   | 9            |
| <i><u>Guidance (FR Notice)</u></i> |                   |                          |  |              |
| D0736                              | 0736              | 08/04/99                 | Update of Guidance Documents at the Food and Drug Administration   | 10           |
| D0497                              | 0497              | 12/03/97                 | Final Guidance on Industry-Supported Scientific and Educational Activities; Notice   | 28           |
| D0489                              | 0489              | 11/21/97                 | Guidance for FDA and Industry: Direct Final Rule Procedures; Notice  | 6            |
| D0513                              | 0513              | 11/01/97                 | Guidance for Industry: Industry Supported Scientific and Educational Activities  | 8            |
| D0328                              | 0328              | 10/08/96                 | Advertising and Promotion; Guidance; Notice  | 2            |
| D0277                              | 0277              | 02/26/96                 | Draft Document Concerning the Regulation of Placental/Umbilical Cord Blood Stem Cell Products Intended for Transplantation or Further Manufacture into Injectable Products; Availability (December 1995 draft document included) | 20           |
| D0222                              | 0222              | 07/11/95                 | FDA Guidance Document Concerning Use of Pilot Manufacturing Facilities for the Development and Manufacture of Biological Products; Availability  | 16           |
| D0214                              | 0214              | 04/06/95                 | Changes to be Reported for Product and Establishment License Applications; Guidance  | 17           |
| D0134                              | 0134              | 11/25/92                 | FDA's Policy Statement Concerning Cooperative Manufacturing Arrangements for Licensed Biologics  | 14           |
| <i><u>Guideline</u></i>            |                   |                          |  |              |
| D0920                              | 0920              | 12/21/00                 | Draft Guidance for Industry: Variances for Blood Collection from Individuals with Hereditary Hemochromatosis   | 6            |
| D0899                              | 0899              | 10/26/00                 | Guidance for Industry: Submitting and Reviewing Complete Responses to Clinical Holds   | 7            |
| D0875                              | 0875              | 08/30/00                 | Draft Guidance for Industry: Analytical Procedures and Methods Validation - Chemistry, Manufacturing and Controls Documentation  | 37           |
| D0836                              | 0836              | 05/26/00                 | PHS Guideline on Infectious Disease Issues in Xenotransplantation  | 58           |

| <i>Hard<br/>Copy</i> | <i>FAX<br/>ID</i> | <i>Document<br/>Date</i> | <i>Title</i>  | <i>Pages</i> |
|----------------------|-------------------|--------------------------|---|--------------|
| D0150                | 0150              | 10/15/93                 | Guideline for Adverse Experience Reporting for Licensed Biological Products   | 55           |
| D0147                | 0147              | 09/28/93                 | Draft Guideline for the Validation of Blood Establishment Computer Systems  | 32           |
| D0108                |                   | 03/01/91                 | Guideline on the Preparation of Investigational New Drug Products (Human & Animal)  | 15           |
| D0098                |                   | 01/01/90                 | Guideline for Determination of Residual Moisture in Dried Biological Products   | 11           |
| D0096                |                   | 10/26/89                 | Guideline for Collection of Blood or Blood Products from Donors With Positive Tests for Infectious Disease Markers ("High Risk" Donors)                                       | 12           |
| D0092                |                   | 09/01/89                 | Guideline for Drug Master Files   | 33           |
| D0084                |                   | 02/01/89                 | Guidelines for Release of Pneumococcal Vaccine, Polyvalent  | 7            |
| D0082                |                   | 11/01/88                 | Draft Guideline for the Design of Clinical Trials for Evaluation of Safety and Efficacy of Allergenic Products for Therapeutic Uses   | 23           |
| D0079                |                   | 10/07/88                 | Revised Guideline for the Collection of Platelets, Pheresis   | 10           |
| D0066                |                   | 12/01/87                 | Guideline On Validation of the Limulus Amebocyte Lysate Test as an End-Product Endotoxin Test for Human and Animal Parenteral Drugs, Biological Products, and Medical Devices | 60           |
| D0064                |                   | 06/01/87                 | Guideline On Sterile Drug Products Produced by Aseptic Processing   | 44           |
| D0063                |                   | 05/01/87                 | Guideline On General Principles of Process Validation   | 26           |
| D0060                |                   | 02/01/87                 | Guideline for Submitting Documentation for Packaging for Human Drugs and Biologics  | 30           |
| D0061                |                   | 02/01/87                 | Guideline for Submitting Documentation for the Stability of Human Drugs and Biologics   | 59           |
| D0053                |                   | 08/01/85                 | Guideline for the Uniform Labeling of Blood and Blood Components  | 81           |
| D0051                |                   | 07/17/85                 | Guidelines for Meningococcal Polysaccharide Vaccines  | 24           |
| D0033                |                   | 08/01/81                 | Revised Guideline for Adding Heparin to Empty Containers for Collection of Heparinized Source Plasma (Human)  | 3            |

| <i>Hard<br/>Copy</i>        | <i>FAX<br/>ID</i> | <i>Document<br/>Date</i> | <i>Title</i>   | <i>Pages</i> |
|-----------------------------|-------------------|--------------------------|--|--------------|
| D0032                       |                   | 07/01/81                 | Platelet Testing Guidelines - Approval of New Procedures and Equipment   | 6            |
| D0031                       |                   | 01/28/81                 | Collection of Human Leukocytes for Further Manufacturing (Source Leukocytes)   | 5            |
| D0030                       |                   | 06/01/80                 | Guidelines for Immunization of Source Plasma (Human) Donors with Blood Substances  | 8            |
| D0029                       |                   | 04/12/79                 | Guidelines for Interpretation of Potency Test Results for All Forms of Adsorbed Diphtheria and Tetanus Toxoids                     | 2            |
| D0028                       |                   | 03/30/78                 | Package Insert: Immune Serum Globulin (Human)  | 7            |
| D0027                       |                   | 07/20/76                 | Guidelines for Reviewing Amendments to Include Plasmapheresis of Hemophiliacs  | 1            |
| D0026                       |                   | 10/02/73                 | Interpretative Guidelines of the Source Plasma (Human) Standards   | 8            |
| <i><u>ICH Guideline</u></i> |                   |                          |  |              |
| D0916                       | 0916              | 12/15/00                 | ICH Guidance for Industry - E11 Clinical Investigation of Medicinal Products in the Pediatric Population                           | 16           |
| D0869                       | 0869              | 08/07/00                 | Draft Guideline on Safety Pharmacology Studies for Human Pharmaceuticals   | 10           |
| D0867                       | 0867              | 08/01/00                 | ICH Good Manufacturing Practice Guide for Active Pharmaceutical Ingredients  | 53           |
| D0876                       | 0876              | 07/20/00                 | ICH Draft Consensus Guideline: Organisation of the Common Technical Document for the Registration of Pharmaceuticals for Human Use | 6            |
| D0877                       | 0877              | 07/20/00                 | ICH Draft Consensus Guideline: The Common Technical Document For the Registration of Pharmaceuticals for Human Use - EFFICACY      | 44           |
| D0878                       | 0878              | 07/20/00                 | ICH Draft Consensus Guideline: The Common Technical Document For the Registration of Pharmaceuticals for Human Use -QUALITY        | 17           |
| D0879                       | 0879              | 07/20/00                 | ICH Draft Consensus Guideline: The Common Technical Document For the Registration of Pharmaceuticals for Human Use -SAFETY         | 114          |
| D0830                       | 0830              | 04/21/00                 | International Conference on Harmonisation; Draft Revised Guidance on Q1A(R) Stability Testing of New Drug Substances and Products  | 8            |

| <i>Hard<br/>Copy</i> | <i>FAX<br/>ID</i> | <i>Document<br/>Date</i> | <i>Title</i>  | <i>Pages</i> |
|----------------------|-------------------|--------------------------|---|--------------|
| D0808                | 0808              | 11/08/99                 | International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use; M4 Common Technical Document; Modules IIA, IIB Nonclinical, Module III Quality, Module IV Nonclinical, Module V Efficacy | 136          |
| D0744                | 0744              | 08/18/99                 | ICH Guidance on Specifications: Test Procedures and Acceptance Criteria for Biotechnological/Biological Products  | 8            |
| D0202                | 0202              | 03/01/95                 | ICH Guideline for Industry: Clinical Safety Data Management: Definitions and Standards for Expedited Reporting  | 16           |
| D0175                |                   | 09/01/94                 | ICH Guideline for Industry: Stability Testing of New Drug Substances and Products   | 20           |
|                      |                   |                          | <u><i>ICH Guideline (FR Notice)</i></u>   |              |
| D0860                | 0860              | 07/20/00                 | International Conference on Harmonisation; Draft Revised Guidance on Impurities in New Drug Substances "Q3A(R)"   | 6            |
| D0861                | 0861              | 07/19/00                 | International Conference on Harmonisation; Draft Revised Guidance on Impurities in New Drug Products "Q3B(R)"   | 7            |
| D0757                | 0757              | 09/24/99                 | ICH Draft Guidance: Choice of Control Group in Clinical Trials  | 14           |
| D0722                | 0722              | 06/25/99                 | ICH Guidance on the Duration of Chronic Toxicity Testing in Animals (Rodent and Nonrodent Toxicity Testing) Availability  | 2            |
| D0623                | 0623              | 09/24/98                 | ICH Guidance on Viral Safety Evaluation of Biotechnology Products Derived From Cell Lines of Human or Animal Origin; Availability   | 11           |
| D0622                | 0622              | 09/21/98                 | ICH Guidance on Quality of Biotechnological / Biological Products: Derivation and Characterization of Cell Substrates Used for Production of Biotechnological / Biological Products; Availability   | 6            |
| D0620                | 0620              | 09/16/98                 | ICH Guidance on Statistical Principles for Clinical Trials; Availability  | 16           |
| D0583                | 0583              | 06/10/98                 | ICH Guidance on Ethnic Factors in the Acceptability of Foreign Clinical Data; Availability  | 7            |
| D0582                | 0582              | 06/09/98                 | ICH Draft Guidance on Specifications: Test Procedures and Acceptance Criteria for Biotechnological / Biological Products  | 8            |

| <i>Hard<br/>Copy</i> | <i>FAX<br/>ID</i> | <i>Document<br/>Date</i> | <i>Title</i>   | <i>Pages</i> |
|----------------------|-------------------|--------------------------|--|--------------|
| D0533                | 0533              | 02/23/98                 | ICH Guidance on Testing for Carcinogenicity of Pharmaceuticals   | 4            |
| D0515                | 0515              | 01/15/98                 | ICH Guidance on Data Elements for Transmission of Individual Case Safety Reports; Availability   | 9            |
| D0499                | 0499              | 12/04/97                 | ICH Guidance on Dose Selection for Carcinogenicity Studies of Pharmaceuticals: Addendum on a Limit Dose and Related Notes; Availability; Notice          | 3            |
| D0492                | 0492              | 11/25/97                 | ICH Guidance on Nonclinical Safety Studies for the Conduct of Human Clinical Trials for Pharmaceuticals; Notice  | 5            |
| D0493                | 0493              | 11/25/97                 | ICH Draft Guidance on Specifications: Test Procedures and Acceptance Criteria for New Drug Substances and New Drug Products: Chemical Substances; Notice | 22           |
| D0488                | 0488              | 11/21/97                 | ICH Guidance on Genotoxicity: A Standard Battery for Genotoxicity Testing of Pharmaceuticals; Availability; Notice                                       | 5            |
| D0486                | 0486              | 11/18/97                 | ICH Guidance on Preclinical Safety Evaluation of Biotechnology-Derived Pharmaceuticals; Availability   | 1            |
| D0419                | 0419              | 05/30/97                 | ICH Draft Guidelines on General Considerations for Clinical Trials; Availability; Notice   | 10           |
| D0414                | 0414              | 05/19/97                 | ICH Guideline on Impurities in New Drug Products, Part IV; Availability; Notice  | 9            |
| D0415                | 0415              | 05/19/97                 | ICH Guideline on the Validation of Analytical Procedures: Methodology, Part V; Availability; Notice  | 5            |
| D0416                | 0416              | 05/19/97                 | ICH Guideline on Clinical Safety Data Management: Periodic Safety Update Reports for Marketed Drugs, Part VI; Availability; Notice                       | 8            |
| D0417                | 0417              | 05/19/97                 | Error Correction: ICH Draft Guideline on Impurities: Residual Solvents; Availability (published 5/2/97)  | 1            |
| D0413                | 0413              | 05/16/97                 | ICH Guideline for the Photostability Testing of New Drug Substances and Products, Part II; Availability; Notice  | 8            |
| D0410                | 0410              | 05/09/97                 | ICH Guideline on Stability Testing for New Dosage Forms; Availability  | 2            |
| D0411                | 0411              | 05/09/97                 | ICH Draft Guideline on Statistical Principles for Clinical Trials, Part III; Notice of Availability  | 16           |
| D0412                | 0412              | 05/09/97                 | ICH Good Clinical Practice: Consolidated Guideline, Part II; Notice of Availability  | 19           |

| <i>Hard<br/>Copy</i>            | <i>FAX<br/>ID</i> | <i>Document<br/>Date</i> | <i>Title</i>   | <i>Pages</i> |
|---------------------------------|-------------------|--------------------------|--|--------------|
| D0404                           | 0404              | 05/02/97                 | ICH Draft Guideline on the Timing of Nonclinical Studies for the Conduct of Human Clinical Trials for Pharmaceuticals; Notice  | 5            |
| D0405                           | 0405              | 05/02/97                 | ICH Draft Guideline on Impurities: Residual Solvents; Availability; Notice   | 9            |
| D0389                           | 0389              | 04/02/97                 | ICH Draft Guideline on Dose Selection for Carcinogenicity Studies of Pharmaceuticals: Addendum on the Limit Dose; Availability   | 2            |
| D0323                           | 0323              | 10/01/96                 | ICH Draft Guideline on Data Elements for Transmission of Individual Case Safety Reports  | 8            |
| D0316                           | 0316              | 08/26/96                 | ICH Revised Guidance; Single Dose Acute Toxicity Testing for Pharmaceuticals   | 3            |
| D0310                           | 0310              | 07/17/96                 | ICH Guideline on Structure and Content of Clinical Study Reports; Availability; Notice   | 25           |
| D0309                           | 0309              | 07/10/96                 | ICH Final Guidelines on Stability Testing of Biotechnological/Biological Products; Availability; Notice  | 5            |
| D0289                           |                   | 04/24/96                 | ICH Guidance on Specific Aspects of Regulatory Genotoxicity Tests for Pharmaceuticals; Availability; Notice  | 6            |
| D0285                           | 0285              | 04/05/96                 | ICH Guideline on the Detection of Toxicity to Reproduction for Medicinal Products: Addendum on Toxicity to Male Fertility; Availability; Notice                              | 3            |
| D0279                           | 0279              | 03/01/96                 | ICH Final Guideline on the Need for Long-Term Rodent Carcinogenicity Study of Pharmaceuticals; Availability  | 4            |
| D0276                           | 0276              | 02/23/96                 | ICH Final Guideline: Quality of Biotechnological Products: Analysis of the Expression Construct in Cells Used for Production of r-DNA Derived Protein Products; Availability | 3            |
| D0170                           |                   | 08/01/94                 | ICH Guideline for Industry: Studies in Support of Special Populations : Geriatrics   | 8            |
| <i><u>Information Sheet</u></i> |                   |                          |  |              |
| D0896                           | 0896              | 10/18/00                 | Availability of Abbott / Murex Single Use Diagnostic System (SUDS) HIV-1 Test  | 2            |
| D0857                           | 0857              | 07/18/00                 | Resumption of Action After Temporary Deferment   | 2            |
| D0845                           | 0845              | 06/20/00                 | Temporary Deferment of Action on Certain Submissions   | 2            |
| D0818                           | 0818              | 03/28/00                 | Options for Alternative Arm Preparation - Clinipad Recall 3/9/2000; (Updated 3/28/2000)  | 3            |

| <i>Hard<br/>Copy</i> | <i>FAX<br/>ID</i> | <i>Document<br/>Date</i> | <i>Title</i>  | <i>Pages</i> |
|----------------------|-------------------|--------------------------|---|--------------|
| D0769                | 0769              | 10/28/99                 | Availability of Influenza Virus Vaccine 1999 - Update 10/28/99  | 1            |
| D0768                | 0768              | 10/19/99                 | Availability of Influenza Virus Vaccine 1999 - Update 10/19/99  | 1            |
| D0765                | 0765              | 10/13/99                 | Availability of Influenza Virus Vaccine 1999 - Update 10/13/99  | 1            |
| D0759                | 0759              | 09/29/99                 | Availability of Influenza Virus Vaccine - 1999  | 2            |
| D0703                | 0703              | 05/07/99                 | Testing Yourself for HIV-1, the Virus That Causes AIDS  | 5            |
| D0689                | 0689              | 03/22/99                 | Update on Abbokinase (Urokinase) - March 22, 1999   | 2            |
| D0684                | 0684              | 03/16/99                 | Update on Abbokinase (Urokinase) - March 16, 1999   | 2            |
| D0654                | 0654              | 12/11/98                 | Difficulties in Obtaining Sufficient Amounts of Urokinase   | 2            |
| D0615                | 0615              | 09/08/98                 | Change to the Guidance Entitled "Revised Precautionary Measures to Reduce the Possible Risk of Transmission of Creutzfeldt-Jakob Disease (CJD) by Blood and Blood Products" | 1            |
| D0617                | 0617              | 09/08/98                 | Withdrawal of "Guidance for Industry: Supplemental Testing and the Notification of Consignees of Donor Test Results for Antibody to Hepatitis C Virus (Anti-HCV)"           | 1            |
| D0409                | 0409              | 07/25/97                 | Testing Yourself for HIV-1, The Virus That Causes AIDS - Home Test Kits Are Available - Updated 7/25/97   | 4            |
| D0382                | 0382              | 03/11/97                 | FDA Warns Michigan Biologics Products Institute of Intention to Revoke Licenses   | 2            |
| D0364                | 0364              | 02/11/97                 | HibTITER - Haemophilus b Conjugate Vaccine (Diphtheria CRM197 Protein Conjugate)  | 1            |
| <i><u>Letter</u></i> |                   |                          |   |              |
| D0913                | 0913              | 11/30/00                 | Letter to Sponsors/Researchers - Fetal Cellular or Tissue Products in Human Clinical Studies  | 2            |
| D0854                | 0854              | 05/31/00                 | Letter to Vaccine Manufacturers Regarding Plans for Continued Use of Thimerosal as a Vaccine Preservative (Update)  | 2            |
| D0831                | 0831              | 04/19/00                 | Letter to Manufacturers of Biological Products: Recommendations Regarding Bovine Spongiform Encephalopathy (BSE)  | 4            |
| D0816                | 0816              | 03/06/00                 | Dear Gene Therapy IND or Master File Sponsor Letter   | 3            |
| D0790                | 0790              | 12/14/99                 | Dear Manufacturer Year 2000 Letter  | 2            |

| <i>Hard Copy</i> | <i>FAX ID</i> | <i>Document Date</i> | <i>Title</i>  | <i>Pages</i> |
|------------------|---------------|----------------------|---|--------------|
| D0774            | 0774          | 11/05/99             | Dear Gene Therapy IND Sponsor / Principal Investigator  | 2            |
| D0773            | 0773          | 11/03/99             | Dear Colleague Letter - Consent Decree With Abbott Laboratories and Q&A's   | 11           |
| D0758            | 0758          | 09/24/99             | Dear Doctor Letter: Important Drug Warning - Potential risk of acute renal failure reported to be associated with administration of Immune Globulin Intravenous (Human) | 6            |
| D0728            | 0728          | 07/06/99             | False Negative Results With Use of Unapproved HIV Rapid Home-Use Test Kit - EZ MedTest  | 2            |
| D0853            | 0853          | 07/01/99             | Letter to Vaccine Manufacturers Regarding Plans for Continued use of Thimerosal as a Vaccine Preservative   | 2            |
| D0724            | 0724          | 06/30/99             | Dear President / CEO / Blood Establishment Director: Year 2000 Letter   | 6            |
| D0673            | 0673          | 02/04/99             | Dear Colleague Letter: Voluntary Recall of Tripedia DTaP Vaccine  | 4            |
| D0665            | 0665          | 01/25/99             | Dear Healthcare Provider: Important Drug Warning: Safety Information Regarding the Use of Abbokinase (Urokinase)  | 2            |
| D0664            | 0664          | 01/01/99             | Dear Export Requester letter: Use of specially designed paper for certificates  | 1            |
| D0660            | 0660          | 12/18/98             | Letter to Viral Vaccine IND Sponsors on Use of PCR-based Reverse Transcriptase Assay  | 4            |
| D0647            | 0647          | 11/13/98             | Dear Doctor Letter: Important Drug Warning: Immune Globulin Intravenous (Human)   | 6            |
| D0646            | 0646          | 11/03/98             | Dear Blood Bank / Transfusion Service Director Letter: Hepatitis C Virus Risk   | 1            |
| D0612            | 0612          | 08/19/98             | Dear Dr. Letter: Albumin Use in Seriously Ill Patients  | 1            |
| D0618            | 0618          | 08/12/98             | Dear Colleague letter- Use of Haemophilus influenzae type b Conjugate Vaccines in Combination With DTaP in Infants  | 1            |
| D0593            | 0593          | 07/24/98             | Dear Colleague Letter: Public Meeting on Section 406(b) of the Food and Drug Administration Modernization Act of 1997 (CBER meeting dates 8/14/98 and 8/28/98)          | 2            |
| D0577            | 0577          | 05/11/98             | Dear Doctor Letter: Standardized Grass Pollen Extracts  | 3            |
| D0524            | 0524          | 01/28/98             | Dear Doctor Letter: Difficulty in Obtaining Immune Globulin Intravenous (Human)   | 5            |

| <i>Hard<br/>Copy</i> | <i>FAX<br/>ID</i> | <i>Document<br/>Date</i> | <i>Title</i>   | <i>Pages</i> |
|----------------------|-------------------|--------------------------|--|--------------|
| D0523                | 0523              | 12/23/97                 | Letter to Allergenic Extract Manufacturers - Standardized Grass Pollen Extracts  | 3            |
| D0540                | 0540              | 12/11/97                 | Letter to Biologic Product Manufacturers - Withdrawal of Human Blood-Derived Materials Because Donors Diagnosed With, or At Increased Risk For, CJD    | 13           |
| D0403                | 0403              | 07/17/97                 | Dear Colleague letter - CBER/FDLI Training Video Conference - "Inspection of Blood Establishments" August 13, 1997                                     | 1            |
| D0422                | 0422              | 05/29/97                 | To Plasma Fractionators - CBER's view on product recalls conducted by the plasma fractionation industry  | 5            |
| D0399                | 0399              | 03/25/97                 | Dear Colleague letter - inviting CBER staff to participate in meetings, conferences, panels and workshops  | 2            |
| D0344                | 0344              | 12/03/96                 | To Biologic Product Manufacturers: Revised procedures for internal labeling review number assignment   | 3            |
| D0329                | 0329              | 10/07/96                 | To All Plasma Derivative Manufacturers and to ABRA: Warning Statement for Plasma Derivative Product Labeling   | 3            |
| D0313                | 0313              | 07/31/96                 | To Manufacturers: HIV-1 Group O  | 2            |
| D0306                | 0306              | 06/13/96                 | To Manufacturers: Implementation of testing for Hepatitis C virus RNA by polymerase chain reaction (PCR) of intramuscular immune globulin preparations | 3            |
| D0294                | 0294              | 05/09/96                 | To Manufacturers of FDA-Regulated Drug/Biological/Device Products, Bovine Spongiform Encephalopathy (BSE)  | 2            |
| D0271                |                   | 01/24/96                 | Requesting all manufacturers immediately to revise warning section for package insert on Thrombin  | 3            |
| D0264                | 0264              | 01/04/96                 | Dear Colleague: Regarding Reverse Transcriptase Activity in Viral Vaccines Produced in Chicken Cells   | 2            |
| D0248                | 0248              | 11/09/95                 | To Specific Sponsors: Changes in Lot Release Requirements for Well-Characterized Therapeutic Recombinant DNA-Derived and Monoclonal Antibody Products  | 2            |
| D0207                | 0207              | 03/14/95                 | To Health Professionals: implementation of testing for HCV RNA by PCR for immune globulin products for intramuscular administration                    | 7            |
| D0206                | 0206              | 03/13/95                 | To Manufacturers of Intramuscular Immune Globulin Products: additional information regarding HCV RNA testing by PCR                                    | 3            |

| <i>Hard Copy</i>   | <i>FAX ID</i> | <i>Document Date</i> | <i>Title</i>   | <i>Pages</i> |
|--------------------|---------------|----------------------|--|--------------|
| D0204              | 0204          | 03/03/95             | To Manufacturers of Intramuscular Immune Globulin Products: HCV RNA testing by PCR   | 2            |
| D0198              | 0198          | 02/10/95             | To Blood Establishment Computer Software Manufacturers   | 5            |
| D0192              | 0192          | 12/27/94             | To Manufacturers of Immune Globulin Products: Testing for Hepatitis C Virus RNA Immunoglobulin   | 2            |
| D0184              | 0184          | 11/15/94             | Dear Colleague: Update on the Status of Efforts to Improve the Efficiency and Effectiveness of the Biologic Product Review and Approval Program                  | 17           |
| D0178              | 0178          | 10/03/94             | To IGIV Manufacturers: Aseptic Meningitis Syndrome   | 3            |
| D0165              | 0165          | 05/26/94             | To Manufacturers of Licensed Anti-HIV Test Kits  | 4            |
| D0164              | 0164          | 05/23/94             | To Sponsors of INDs for Human Immunoglobulin Products  | 4            |
| D0162              | 0162          | 03/31/94             | To Blood Establishment Computer Software Manufacturers   | 3            |
| D0155              | 0155          | 12/28/93             | To Whom It May Concern: Response to Concerns Regarding Interpretation of the Interim Final Rule Concerning Banked Human Tissue Intended for Transplantation      | 3            |
| D0153              | 0153          | 12/17/93             | To Manufacturers: Bovine Derived Materials (BSE)   | 3            |
| D0146              | 0146          | 09/20/93             | To Sponsors of INDs using Retroviral Vectors   | 2            |
| D0361              |               | 05/03/91             | To Biologic Product Manufacturers - controlling materials of bovine or ovine origin  | 2            |
| <i><u>List</u></i> |               |                      |  |              |
| D9001              | 9001          | 06/01/01             | Documents Available From CBER (Updated monthly)  | 58           |
| D9998              | 9998          | 06/01/01             | CBER FAX Information System - Documents Added in the Last 30 Days  | 1            |
| D9999              | 9999          | 06/01/01             | Documents Available from the CBER FAX Information System (Updated Monthly)   | 48           |
| D9997              | 9997          | 05/08/01             | CBER FAX Information System - Recalls, Market Withdrawals, Safety Issues   | 10           |
| D9002              | 9002          | 07/29/97             | Memorandum and Related Documents Pertaining to Human Blood & Blood Products Available from CBER's Office of Communication, Training and Manufacturers Assistance | 4            |
| D9003              | 9003          | 05/05/97             | Guidance Documents Applicable to the Center for Drug Evaluation and Research (CDER)  | 30           |

| <i>Hard<br/>Copy</i>             | <i>FAX<br/>ID</i> | <i>Document<br/>Date</i> | <i>Title</i>  | <i>Pages</i> |
|----------------------------------|-------------------|--------------------------|---|--------------|
| <u><i>Meeting Notice</i></u>     |                   |                          |   |              |
| D0503                            | 0503              | 12/15/97                 | Developing U.S. Public Health Service Policy in Xenotransplantation - Meeting January 21 & 22, 1998   | 2            |
| D0423                            | 0423              | 06/06/97                 | Cross Species Infectivity and Pathogenesis, July 21-22, 1997  | 1            |
| D0360                            | 0360              | 01/15/97                 | Simian Virus 40 (SV40) - A Possible Human Polyomavirus (January 27-28, 1997)  | 2            |
| <u><i>Memo</i></u>               |                   |                          |   |              |
| D0215                            | 0215              | 04/06/95                 | To Licensed Manufacturers: Extended Expiration Dating of U.S. Standard Pertussis Vaccine, Lot No. 11  | 1            |
| D0056                            |                   | 12/06/85                 | To In Vitro Diagnostic Reagent Manufacturers: Guidance On the Labeling of Human Blood Derived In Vitro Diagnostic Devices In Regard to Labeling for HTLV-III/LAV Antibody Testing | 2            |
| <u><i>Performance</i></u>        |                   |                          |   |              |
| D0308                            | 0308              | 09/30/97                 | CBER User Fee Performance Goals   | 14           |
| D0266                            | 0266              | 01/16/96                 | FDA Talk Paper: FDA 1995 Approvals; 1995 CBER Approval Actions  | 6            |
| D0261                            | 0261              | 01/02/96                 | CBER Annual Report FY95   | 52           |
| D0193                            | 0193              | 01/17/95                 | 1994 CBER Approval Actions and FDA Talk Paper - 1994 Medication Approvals   | 7            |
| D0157                            | 0157              | 01/13/94                 | FDA Drug and Biologics Approvals - 1993   | 9            |
| <u><i>Points to Consider</i></u> |                   |                          |   |              |
| D0372                            | 0372              | 02/28/97                 | PTC in the Manufacture and Testing of Monoclonal Antibody Products for Human Use  | 47           |
| D0336                            | 0336              | 12/22/96                 | PTC on Plasmid DNA Vaccines for Preventive Infectious Disease Indications   | 36           |
| D0262                            | 0262              | 01/02/96                 | Draft Addendum to the PTC in Human Somatic Cell and Gene Therapy  | 18           |
| D0236                            | 0236              | 08/22/95                 | PTC in the Manufacture and Testing of Therapeutic Products for Human Use Derived from Transgenic Animals  | 20           |
| D0139                            | 0139              | 07/12/93                 | PTC in the Characterization of Cell Lines Used to Produce Biologicals   | 42           |

| <i>Hard<br/>Copy</i>                     | <i>FAX<br/>ID</i> | <i>Document<br/>Date</i> | <i>Title</i>   | <i>Pages</i> |
|--|-------------------|--------------------------|--|--------------|
| D0126                                    | 0126              | 04/06/92                 | Supplement to the PTC in the Production and Testing of New Drugs and Biologicals Produced by Recombinant DNA Technology: Nucleic Acid Characterization and Genetic Stability | 9            |
| D0124                                    |                   | 03/01/92                 | PTC in the Manufacture of In Vitro Monoclonal Antibody Products for Further Manufacturing into Blood Grouping Reagent and Anti-Human Globulin                                | 16           |
| D0125                                    |                   | 03/01/92                 | PTC in the Design and Implementation of Field Trials for Blood Grouping Reagents and Anti-Human Globulin   | 7            |
| D0115                                    | 0115              | 08/27/91                 | Draft PTC in Human Somatic Cell Therapy and Gene Therapy   | 21           |
| D0104                                    |                   | 08/21/90                 | PTC in the Safety Evaluation of Hemoglobin- Based Oxygen Carriers  | 9            |
| D0102                                    |                   | 04/02/90                 | Cytokine and Growth Factor Pre-Pivotal Trial Information Package   | 23           |
| D0090                                    |                   | 08/22/89                 | PTC in the Collection, Processing and Testing of Ex Vivo Activated Mononuclear Leukocytes for Administration to Humans   | 21           |
| D0089                                    | 0089              | 08/08/89                 | Draft PTC in the Manufacture and Clinical Evaluation of In Vitro Tests to Detect Antibodies to Human Immunodeficiency Virus Type 1 (1989)                                    | 25           |
| D0048                                    | 0048              | 04/10/85                 | Draft PTC in the Production and Testing of New Drugs and Biologicals Produced by Recombinant DNA Technology  | 14           |
| D0039                                    | 0039              | 07/28/83                 | Draft PTC in the Production and Testing of Interferon Intended for Investigational Use in Humans (Interferon Test Procedures)  | 21           |
| D0038                                    |                   | 06/20/83                 | PTC in the Manufacture of In Vitro Monoclonal Antibody Products Subject to Licensure   | 5            |
| <i><u>Public Hearing</u></i>             |                   |                          |  |              |
| D0250                                    |                   | 11/16/95                 | Products Comprised of Living Autologous Cells Manipulated Ex Vivo and Intended for Structural Repair or Reconstruction   | 94           |
| <i><u>Recall/ Withdrawal/ Safety</u></i> |                   |                          |  |              |
| D0955                                    | 0955              | 05/08/01                 | Recall of Antibody to Human Immunodeficiency Virus Type 1 p24 Antigen Test Dits, (HIVAG-1 Monoclonal), (Abbott Laboratories)   | 1            |
| D0952                                    | 0952              | 04/18/01                 | Recall of Dornase alfa, (Pulmozyme) (Genentech, Inc.)  | 1            |

| <i>Hard<br/>Copy</i> | <i>FAX<br/>ID</i> | <i>Document<br/>Date</i> | <i>Title</i>  | <i>Pages</i> |
|----------------------|-------------------|--------------------------|---|--------------|
| D0949                | 0949              | 04/16/01                 | Recall of ABS2000 Automated Blood Bank Instrument - (Immucor, Inc.)   | 1            |
| D0948                | 0948              | 04/10/01                 | Voluntary Recall of BCG, Live (PACIS) - (Biochem Pharma, Inc.)  | 1            |
| D0947                | 0947              | 04/03/01                 | Voluntary Recall of Limulus Amebocyte Lysate (LAL) - (Associates of Cape Cod)                                       | 1            |
| D0944                | 0944              | 03/29/01                 | Firm Initiated Recall of Reagent Red Blood Cells (Immucor)  | 2            |
| D0941                | 0941              | 03/16/01                 | Voluntary Recall of Rabies Vaccine, RabAvert (Chiron Behring GmbH & Co.)  | 1            |
| D0953                | 0953              | 03/12/01                 | Recall of Collagenase (Santyl Ointment)   | 1            |
| D0940                | 0940              | 02/22/01                 | Voluntary Recall of Hepatitis B Vaccine (Recombinant), Engerix-B (Glaxo SmithKline Beecham)                         | 1            |
| D0936                | 0936              | 02/13/01                 | Firm Initiated Recall of HIV p24 Antigen Test Kit (Abbott Laboratories)   | 1            |
| D0933                | 0933              | 02/12/01                 | Firm Initiated Recall of Hormodendrum Cladosporioides Allergenic Extract (Allergy Laboratories, Inc.)               | 1            |
| D0908                | 0908              | 11/13/00                 | Voluntary Recall of Mumps Skin Test Antigen (Aventis Pasteur Inc)   | 1            |
| D0900                | 0900              | 10/24/00                 | Voluntary Recall of Immune Globulin Intravenous (Human) Iveegam EN, 5000 mg (Baxter Healthcare Corp.)               | 1            |
| D0894                | 0894              | 10/11/00                 | Voluntary Recall of Dornase alfa (Pulmozyme, Inhalation Solution) (Genentech, Inc.)                                 | 1            |
| D0902                | 0902              | 10/03/00                 | Voluntary Recall of Allergenic Extract - Tuna, for Scratch, Prick or Puncture Testing (Hollister-Stier Labs LLC)    | 1            |
| D0889                | 0889              | 09/28/00                 | Voluntary Recall of Urokinase, 9000 IU, for Catheter Clearance (Medicine Shoppe)                                    | 1            |
| D0888                | 0888              | 09/22/00                 | Firm Initiated Recall of Red Blood Cell Leukoreduction Filters; FDA considers the risk of bacteremia to be very low | 1            |
| D0887                | 0887              | 09/21/00                 | Voluntary Recall of Diagnostic Allergenic Extracts (Hollister-Stier Labs LLC)                                       | 1            |
| D0886                | 0886              | 09/18/00                 | Firm Initiated Recall of Red Blood Cell Leukoreduction Filters (Baxter Healthcare Corp)                             | 1            |

| <i>Hard<br/>Copy</i> | <i>FAX<br/>ID</i> | <i>Document<br/>Date</i> | <i>Title</i>   | <i>Pages</i> |
|----------------------|-------------------|--------------------------|--|--------------|
| D0884                | 0884              | 09/01/00                 | Voluntary Recall of Albumin (Human) (Bioport Corp.)  | 1            |
| D0885                | 0885              | 09/01/00                 | Voluntary Recall of Diphtheria & Tetanus Toxoids Absorbed (Bioport Corp.)  | 1            |
| D0880                | 0880              | 08/30/00                 | Firm Initiated Recall of Haemophilus b Conjugate Vaccine (HibTITER)  | 1            |
| D0883                | 0883              | 08/30/00                 | Voluntary Recall of Anthrax Vaccine Absorbed (Bioport Corp)  | 1            |
| D0881                | 0881              | 08/28/00                 | Voluntary Recall of Collagenase, Santyl Ointment 30 gram tube, 250 ABC units per gram (Advance Biofactures Corp)   | 1            |
| D0871                | 0871              | 08/14/00                 | Voluntary Recall of Anti-thymocyte Globulin (Rabbit), Thymoglobulin (IMTIX SangStat Medical Corp) - CORRECTION   | 1            |
| D0870                | 0870              | 08/08/00                 | Voluntary Recall of Fibrin Sealant Vapor Heated, Tisseel VH, Two-Component Kit, 2.0 mL (Baxter Healthcare Corp)  | 1            |
| D0863                | 0863              | 07/28/00                 | Voluntary Recall of Rabies Vaccine, IMOVAX Rabies I.D. (Aventis Pasteur, Inc.)   | 1            |
| D0862                | 0862              | 07/27/00                 | Withdrawal of Antihemophilic Factor (Recombinant) (Bayer Corporation) - Updated  | 1            |
| D0891                | 0891              | 07/21/00                 | Voluntary Recall of Blood Establishment Computer Software (Department of Defense)  | 1            |
| D0844                | 0844              | 06/14/00                 | Firm Initiated Recall of Interferon alfa-2a (Recombinant) (Roferon-A) (Hoffman-La Roche)   | 1            |
| D0841                | 0841              | 06/06/00                 | Withdrawal of Sandoglobulin, Immune Globulin Intravenous (Human) - (Central Lab Blood Transf Serv, Swiss Red Cross)  | 1            |
| D0837                | 0837              | 05/31/00                 | Voluntary Recall Of Sandoglobulin, Immune Globulin Intravenous (Human) - (Central Lab Bld Transf Serv, Swiss Red Cross)  | 1            |
| D0829                | 0829              | 03/20/00                 | Firm Initiated Recall of Clinipad's Steri Wipes (alcohol swabs) packaged with Coagulation Factor IX (Human), Mononine, and Antihemophilic Factor (Human), Monoclote-P - (Aventis L.L.C.) | 2            |
| D0806                | 0806              | 02/10/00                 | Voluntary Recall of Albumin (Human) - (Immuno US)  | 1            |
| D0766                | 0766              | 10/15/99                 | Withdrawal of Rotavirus Vaccine, Live, Oral, Tetravalent (RotaShield) (Wyeth Labs Inc.)  | 1            |

| <i>Hard<br/>Copy</i> | <i>FAX<br/>ID</i> | <i>Document<br/>Date</i> | <i>Title</i>   | <i>Pages</i> |
|----------------------|-------------------|--------------------------|--|--------------|
| D0751                | 0751              | 08/24/99                 | Firm Initiated Recall of Immune Globulin Intravenous (Human), (Central Lab Bld Transf Serv Swiss Red Cross)  | 1            |
| D0750                | 0750              | 08/20/99                 | Firm Initiated Recall of Immune Globulin Intravenous (Human), (Central Lab Bld Transf Serv Swiss Red Cross)  | 1            |
| D0725                | 0725              | 07/01/99                 | URGENT BIOLOGIC FIELD CORRECTION of Immune Globulin Intravenous (Human) (Alpha Therapeutic Corp)   | 3            |
| D0718                | 0718              | 06/16/99                 | Voluntary Withdrawal of Cytomegalovirus Immune Globulin (Massachusetts Public Health Biol Lab)   | 1            |
| D0716                | 0716              | 06/11/99                 | URGENT REQUEST for QUARANTINE of Immune Globulin Intravenous (Human) (Alpha Therapeutic Corp)  | 1            |
| D0706                | 0706              | 05/11/99                 | Voluntary Recall of Pooled Plasma, Solvent Detergent Treated, PLAS+SD (V.I.Technologies Inc)   | 2            |
| D0702                | 0702              | 05/04/99                 | Voluntary Recall of Pooled Plasma, Solvent Detergent Treated, PLAS+SD (V.I. Technologies Inc)  | 1            |
| D0694                | 0694              | 04/16/99                 | Voluntary Recall of Pooled Plasma, Solvent Detergent Treated, PLAS+SD (V.I. Technologies Inc)  | 1            |
| D0668                | 0668              | 01/27/99                 | Firm Initiated Recall of Diphtheria and Tetanus Toxoids and Acellular Pertussis Vaccine, Adsorbed (Connaught Laboratories, Inc.)   | 1            |
| D0662                | 0662              | 12/22/98                 | Withdrawal of Antihemophilic Factor (Human) Because Donor Diagnosed with CJD (Centeon Pharma GMBH)   | 1            |
| D0659                | 0659              | 12/16/98                 | Withdrawal of Antihemophilic Factor (Human) and Factor IX Complex Because Donor Diagnosed with CJD (Bayer Corp)  | 1            |
| D0639                | 0639              | 10/30/98                 | Recall of Immune Globulin Intravenous (Human), Antihemophilic Factor (Human), Coagulation Factor IX (Human), Factor IX Complex, Albumin (Human), and Alpha-1 Proteinase Inhibitor (Human) (Alpha Therapeutic Corp) | 6            |
| D0635                | 0635              | 10/23/98                 | Firm Initiated Recall of Immune Globulin Intravenous (Human) (Alpha Therapeutic Corp)  | 1            |
| D0629                | 0629              | 10/02/98                 | Firm Initiated Recall of 1 Lot of Immune Globulin Intravenous (Human), Gammar P.I.V. (Centeon LLC)   | 1            |
| D0624                | 0624              | 09/25/98                 | Firm Initiated Recall of 2 Lots of Albumin (Human) - (Bayer Corp)  | 1            |

| <i>Hard<br/>Copy</i> | <i>FAX<br/>ID</i> | <i>Document<br/>Date</i> | <i>Title</i>  | <i>Pages</i> |
|----------------------|-------------------|--------------------------|---|--------------|
| D0607                | 0607              | 08/14/98                 | Recall of a Single Lot of Sterile Water Injection used as Diluent with Immune Globulin Intravenous (Human) (Centeon LLC)                                    | 1            |
| D0590                | 0590              | 07/09/98                 | Withdrawal of Immune Globulin Intravenous (Human) and Albumin (Human) Because Donor at Increased Risk for CJD (Central Lab Bld Transf Serv Swiss Red Cross) | 1            |
| D0572                | 0572              | 05/15/98                 | Withdrawal of Immune Globulin Intravenous (Human) Because Donor at Increased Risk for CJD (Central Lab Bld Transf Serv Swiss Red Cross)                     | 1            |
| D0595                | 0595              | 05/08/98                 | Firm Initiated Recall of Albumin (Human) and Plasma Protein Fraction (Human) Administration Sets (Alpha Ther Corp)  | 1            |
| D0555                | 0555              | 04/22/98                 | Withdrawal of Varicella-Zoster Immune Globulin (Human) and Immune Globulin (Human) (Mass Public Health Biologic Lab)  | 1            |
| D0550                | 0550              | 04/16/98                 | Withdrawal of Plasma Protein Fraction (Human) Because Donor Diagnosed with CJD (Baxter Healthcare Corp)   | 1            |
| D0549                | 0549              | 04/08/98                 | Withdrawal of Immune Globulin Intravenous (Human) Because Donor at Increased Risk for CJD (Central Lab Bld Transf Serv Swiss Red Cross)                     | 1            |
| D0548                | 0548              | 04/02/98                 | Withdrawal of Immune Globulin Intravenous (Human) Because Donor at Increased Risk for CJD (Central Lab Bld Transf Serv Swiss Red Cross)                     | 1            |
| D0546                | 0546              | 03/27/98                 | Withdrawal of Albumin (Human) Because Donor at Increased Risk for CJD (Baxter Healthcare Corp)  | 1            |
| D0545                | 0545              | 03/24/98                 | Withdrawal of Immune Globulin Intravenous (Human) Because Donors at Increased Risk for CJD (Central Lab Bld Transf Serv Swiss Red Cross)                    | 1            |
| D0537                | 0537              | 03/09/98                 | Voluntary Recall of Rho(D) Immune Globulin (Ortho Diagnostic Systems Inc.)  | 1            |
| D0536                | 0536              | 03/06/98                 | Withdrawal of Albumin (Human) Because Donor at Increased Risk for CJD (Central Lab Bld Transf Serv Swiss Red Cross) - RESCINDED 3/6/98                      | 1            |
| D0534                | 0534              | 02/20/98                 | Withdrawal of Immune Globulin Intravenous (Human) Because Donor Diagnosed With CJD (Central Lab Bld Transf Serv Swiss Red Cross)                            | 1            |
| D0532                | 0532              | 02/13/98                 | Withdrawal of Alpha-1-Proteinase Inhibitor (Human), Prolastin, Because Donor Diagnosed with CJD (Bayer Corp)  | 1            |

| <i>Hard<br/>Copy</i> | <i>FAX<br/>ID</i> | <i>Document<br/>Date</i> | <i>Title</i>  | <i>Pages</i> |
|----------------------|-------------------|--------------------------|---|--------------|
| D0528                | 0528              | 02/10/98                 | Withdrawal of Eight Plasma Derivative Products Because Donor Diagnosed With CJD (Baxter Healthcare Corp)  | 2            |
| D0527                | 0527              | 02/03/98                 | Withdrawal of Lymphocyte Immune Globulin, Anti-Thymocyte Globulin (Equine), ATGAM Sterile Solution, Because Donor Diagnosed with CJD (Pharmacia & Upjohn)                               | 1            |
| D0514                | 0514              | 01/14/98                 | Withdrawal of Albumin (Human) and Immune Globulin Intravenous (Human) Because Donor Diagnosed With CJD (Central Lab Bld Transf Serv, Swiss Red Cross)                                   | 2            |
| D0506                | 0506              | 01/09/98                 | Recall of Albumin (Human), 25% (Bayer Corp)   | 1            |
| D0494                | 0494              | 11/25/97                 | Withdrawal of Immune Globulin Intravenous (Human) Sandoglobulin, and Albumin (Human) Because Donor at Increased Risk for CJD (Central Lab Bld Transf Serv, Swiss Red Cross)             | 1            |
| D0482                | 0482              | 10/21/97                 | Withdrawal of Immune Globulin Intravenous (Human), Sandoglobulin, Because Donor Diagnosed with CJD (Central Lab Bld Transf Serv, Swiss Red Cross)                                       | 1            |
| D0480                | 0480              | 10/16/97                 | Withdrawal of Alpha-1-Proteinase Inhibitor (Human), Prolastin, Because Donor Diagnosed With CJD (Bayer Corp)  | 1            |
| D0481                | 0481              | 10/16/97                 | Recall of Rho(D) Immune Globulin (Human) RhoGAM (Ortho Diag Sys Inc)  | 1            |
| D0479                | 0479              | 10/15/97                 | Withdrawal of Eight Derivative Products Because Donor Diagnosed With CJD (Baxter Healthcare Corp)   | 3            |
| D0476                | 0476              | 10/10/97                 | Withdrawal of Immune Globulin Intravenous (Human) Because Donors at Increased Risk for CJD (Central Lab Bld Transf Serv Swiss Red Cross)  | 1            |
| D0472                | 0472              | 10/02/97                 | Withdrawal of Albumin (Human) and Immune Globulin Intravenous (Human) and Intermediate Products Because Donors at Increased Risk for CJD (Baxter Healthcare Corp) - Updated 5/21/98     | 2            |
| D0471                | 0471              | 10/01/97                 | Withdrawal of Albumin (Human) and Immune Globulin Intravenous (Human) Because Donor at Increased Risk for CJD (Central Lab Bld Transf Serv Swiss Red Cross)                             | 1            |
| D0466                | 0466              | 09/17/97                 | Withdrawal of Six Derivative Products Because Donors at Increased Risk for CJD (Baxter Healthcare Corp)   | 2            |
| D0465                | 0465              | 09/09/97                 | Withdrawal of Immune Globulin Intravenous (Human), Albumin (Human) and Coagulation Factor IX (Human) Because Donor at Increased Risk for CJD (Alpha Therapeutic Corp) - Updated 9/10/97 | 2            |

| <i>Hard<br/>Copy</i> | <i>FAX<br/>ID</i> | <i>Document<br/>Date</i> | <i>Title</i>  | <i>Pages</i> |
|----------------------|-------------------|--------------------------|---|--------------|
| D0462                | 0462              | 09/03/97                 | Withdrawal of Albumin (Human) and Immune Globulin Intravenous (Human) Because Donor Diagnosed With CJD (Central Lab Bld Transf Serv Swiss red Cross)                                  | 1            |
| D0455                | 0455              | 08/19/97                 | Withdrawal of Two Lots of Alpha-1-Proteinase Inhibitor (Human), Prolastin, Because Donors at Increased Risk for CJD (Bayer Corp)  | 1            |
| D0450                | 0450              | 08/16/97                 | Withdrawal of Seven Derivative Products Because Donors at Increased Risk for CJD (Baxter Healthcare Corp and Central Lab Bld Transf Serv Swiss Red Cross)                             | 2            |
| D0444                | 0444              | 07/31/97                 | Withdrawal of Alpha-1-Proteinase Inhibitor (Human) Because Donor at Increased Risk for CJD (Bayer Corp)   | 1            |
| D0446                | 0446              | 07/30/97                 | Withdrawal of Immune Globulin Intravenous (Human), Sandoglobulin, Because Donor at Increased Risk for CJD (Central Lab Bld Trans Serv Swiss Red Cross)                                | 1            |
| D0443                | 0443              | 07/29/97                 | Withdrawal of Nine Derivative Products Because Donor at Increased Risk for CJD (Baxter Healthcare Corp & Central Lab Bld Transf Serv Swiss Red Cross)                                 | 3            |
| D0435                | 0435              | 07/22/97                 | Withdrawal of Seven Derivative Products Because Donor at Increased Risk for CJD (Baxter Healthcare Corp.)   | 2            |
| D0430                | 0430              | 07/16/97                 | Withdrawal of Immune Globulin Intravenous (Human) and Albumin (Human) Because Donor Diagnosed With CJD (Central Lab Bld Transf Serv Swiss Red Cross) - Updated 7/17/97                | 1            |
| D0433                | 0433              | 07/15/97                 | Recall of Immune Globulin Intravenous (Human), Albumin (Human) and Plasma Protein Fraction (Human) Because Donor at Increased Risk for CJD (Baxter Healthcare Corp) - Updated 5/21/98 | 1            |
| D0431                | 0431              | 07/12/97                 | Recall of Three Lots of Antihemophilic Factor (Recombinant), Recombinate (updated 7/14/97) (Baxter Healthcare Corp)   | 1            |
| D0429                | 0429              | 07/07/97                 | Recall of Blood Products In Six States Due to Risk of Tick-Borne Illnesses  | 2            |
| D0428                | 0428              | 06/26/97                 | Recall of 2 lots of Rho(D) Immune Globulin (Human) (Bayer Corp)   | 1            |
| D0418                | 0418              | 05/24/97                 | Class III Recall of Antihemophilic Factor (Human), Method M, Monoclonal Purified (Baxter Healthcare Corp) - Updated 6/4/97  | 1            |
| D0408                | 0408              | 05/06/97                 | Recall of Cytomegalovirus Immune Globulin Intravenous (Human) (Massachusetts Public Health Biologic Labs)   | 1            |

| <i>Hard<br/>Copy</i> | <i>FAX<br/>ID</i> | <i>Document<br/>Date</i> | <i>Title</i>   | <i>Pages</i> |
|----------------------|-------------------|--------------------------|--|--------------|
| D0400                | 0400              | 04/23/97                 | Recall of Immune Globulin Intravenous (Human) Solvent Detergent Treated, Gammagard S/D (Baxter Healthcare Corp)  | 1            |
| D0398                | 0398              | 04/15/97                 | Withdrawal of Alpha-1-Proteinase Inhibitor (Human) Because Donors at Increased Risk for, or Diagnosed with, CJD (Bayer Corp)   | 1            |
| D0397                | 0397              | 04/14/97                 | Withdrawal of Plasma Derivative Products Because Donors at Increased Risk for, or Diagnosed with, CJD (Baxter Healthcare Corp)                                       | 2            |
| D0385                | 0385              | 03/25/97                 | Recall of Thrombin, Thrombostat (Parke-Davis)  | 1            |
| D0386                | 0386              | 03/25/97                 | Withdrawal of Four Plasma Derivative Products Due to the Possibility of the Transmission of CJD (Baxter Healthcare Corp) - Updated 5/21/98                           | 1            |
| D0387                | 0387              | 03/25/97                 | Withdrawal of Albumin (Human) and Fraction IV-1 Paste Due to the Possibility of the Transmission of CJD (Baxter Healthcare Corp)                                     | 1            |
| D0396                | 0396              | 03/20/97                 | Withdrawal of Albumin (Human) and Immune Globulin Intravenous (Human) Products Because Donor at Increased Risk for CJD (Central Lab Bld Transf Serv Swiss Red Cross) | 1            |
| D0381                | 0381              | 03/10/97                 | Further Information Regarding Recall of Single Lot of Immune Globulin Intravenous (Human) Venoglobulin-S, Lot GL7503A (Alpha Therapeutic Corp)                       | 1            |
| D0380                | 0380              | 03/07/97                 | Recall of Single Lot of Immune Globulin Intravenous (Human) Venoglobulin-S, Lot GL7503A (Alpha Therapeutic Corp)   | 1            |
| D0375                | 0375              | 03/03/97                 | Voluntary Recall of Single Lot of Coagulation Factor IX (Human) Mononine, Lot P13609 (Centeon LLC)   | 1            |
| D0370                | 0370              | 02/26/97                 | Voluntary Recall of Single Lot of Antihemophilic Factor (Human) Monoclote-P Lot P68201 (Centeon LLC)   | 1            |
| D0368                | 0368              | 02/19/97                 | Quarantine of Single Lot of Alpha Factor IX Complex, ProfilnineSD  | 1            |
| D0369                | 0369              | 02/19/97                 | Withdrawal of Plasma Derivative Products Due to the Possibility of the Transmission of Creutzfeldt-Jakob Disease (CJD) (Baxter Healthcare Corp)                      | 1            |
| D0365                | 0365              | 02/12/97                 | Voluntary Recall of Fluogen, Influenza Virus Vaccine, Trivalent, Types A and B   | 1            |
| D0363                | 0363              | 01/22/97                 | Alpha-1 Proteinase Inhibitor Withdrawal (Bayer Corp)   | 1            |
| D0367                | 0367              | 01/16/97                 | Immune Globulin Intravenous (Human), Sandoglobulin (Central Lab Bld Transf Serv Swiss Red Cross)   | 1            |

| <i>Hard<br/>Copy</i>            | <i>FAX<br/>ID</i> | <i>Document<br/>Date</i> | <i>Title</i>  | <i>Pages</i> |
|---------------------------------|-------------------|--------------------------|---|--------------|
| D0573                           | 0573              | 01/13/97                 | Withdrawal of Plasma Derivative Products Because Donors at Increased Risk for CJD (Baxter Healthcare Corp) - Updated 5/21/98                                  | 2            |
| D0355                           | 0355              | 01/02/97                 | Albumin Products Withdrawn Due to the Possibility of the Transmission of Creutzfeldt-Jakob Disease (CJD) (multiple manufacturers)                             | 3            |
| D0356                           | 0356              | 01/02/97                 | Partially Manufactured Pastes Withdrawn Due to the Possibility of Transmission of Creutzfeldt-Jakob Disease (CJD) (multiple manufacturers)                    | 2            |
| D0354                           | 0354              | 12/16/96                 | Letter To Health Care Providers: Recommendations from the CDC and FDA Regarding 1996-1997 Influenza Virus Vaccine   | 2            |
| D0341                           | 0341              | 11/06/96                 | Use of Recalled Albumin (Human) in the Manufacture of Products  | 7            |
| D0337                           | 0337              | 11/04/96                 | Recall of Swiss Red Cross Albumin Lot # 6.231.026.0   | 1            |
| D0335                           | 0335              | 10/24/96                 | Public Notification of Withdrawals and Recalls of Plasma Derived Products 11/19/96 NIH  | 2            |
| D0332                           | 0332              | 10/09/96                 | FDA Advises Public of Voluntary Worldwide Recall of All Albuminar and Plasma-Plex Manufactured by Centeon, L.L.C.   | 2            |
| D0327                           | 0327              | 10/04/96                 | Recall of Antihemophilic Factor (Factor VIII) (Centeon LLC)   | 2            |
| D0325                           | 0325              | 10/03/96                 | Recall of Albumin Expanded  | 2            |
| D0312                           | 0312              | 06/14/96                 | To Health Professionals: Withdrawal of some immune globulin products for intramuscular administration because of certain safety issues                        | 9            |
| D0213                           | 0213              | 03/31/95                 | Dear Colleague: Plasma Product Withdrawal Associated with Probable Creutzfeldt-Jakob Disease (CJD) Donor (Addendum to 3/29/95 letter to Health Professionals) | 4            |
| D0212                           | 0212              | 03/29/95                 | To Health Professionals: Market Withdrawal - Plasma Product Produced from Blood Derived from a Donor with Probable Creutzfeldt-Jakob Disease (CJD)            | 5            |
| D0160                           | 0160              | 02/25/94                 | Immune Globulin Intravenous Removed From World Market (Baxter - possible implication in transmission of hepatitis)  | 2            |
| <i><u>Reviewer Guidance</u></i> |                   |                          |   |              |
| D0286                           | 0286              | 01/13/97                 | Reviewer Guidance for a Premarket Notification Submission for Blood Establishment Computer Software   | 7            |

| <i>Hard<br/>Copy</i>               | <i>FAX<br/>ID</i> | <i>Document<br/>Date</i> | <i>Title</i>  | <i>Pages</i> |
|------------------------------------|-------------------|--------------------------|---|--------------|
| D0241                              | 0241              | 10/01/95                 | Informed Consent for Plasmapheresis/Immunization  | 4            |
| D0242                              | 0242              | 10/01/95                 | Disease Associated Antibody Collection Program  | 2            |
| D0243                              | 0243              | 10/01/95                 | Draft Reviewers' Guide: Changes in Personnel  | 1            |
| D0216                              | 0216              | 04/26/95                 | Reviewer Guidance, Computer Software  | 4            |
| <u><i>Slides/ Presentation</i></u> |                   |                          |   |              |
| D0474                              | 0474              | 09/24/97                 | 601.12 Open Public Meeting - Slides / Table   | 25           |
| D0467                              | 0467              | 09/23/97                 | Biologics and Biotechnology Regulation 1997 CBER<br>Perspective CBER, FDA PDA September 23, 1997  | 43           |
| D0426                              | 0426              | 06/05/97                 | IBC Conference on Well Characterized Biologics - 1997<br>PTC in the Manufacture and Testing of Monoclonal<br>Antibody Products for Human Use- 6/5/97            | 16           |
| D0345                              | 0345              | 12/10/96                 | FDLI Annual Educational Conference - CBER Update<br>(Dr. Zoon)  | 7            |
| D0346                              | 0346              | 12/10/96                 | FDLI Annual Educational Conference - CBER Breakout<br>Session (Dr. Devine)  | 25           |
| D0347                              | 0347              | 12/10/96                 | FDLI Annual Educational Conference - Technologies<br>Emerging to Patient Centered Therapies (Dr. Noguchi)   | 12           |
| D0348                              | 0348              | 12/10/96                 | FDLI Annual Educational Conference - CBER Handout:<br>Status of Regulation of Blood and Blood Products<br>(Mary Gustafson)                                      | 5            |
| D0349                              | 0349              | 12/10/96                 | FDLI Annual Educational Conference - CBER Handout:<br>Current Operations and REGO Impact on Inspections<br>(Margaret Tart)                                      | 9            |
| D0321                              | 0321              | 09/11/96                 | Overall Policy Toward Tissue Regulations: Current<br>and Contemplated FDA Requirements for Human<br>Tissue - American Association of Tissue Banks (Dr.<br>Zoon) | 10           |
| D0320                              | 0320              | 09/10/96                 | Biologics 1996 - RAPS (Dr. Zoon)  | 5            |
| D0268                              | 0268              | 01/18/96                 | Reinventing CBER 1996, Northwest Biotech (Dr. Zoon)   | 12           |
| D0267                              | 0267              | 01/16/96                 | Reinventing CBER 1996, BioEast (Dr. Zoon)   | 6            |
| D0258                              | 0258              | 12/11/95                 | Well-Characterized Biotechnology Products: Evolving<br>to Meet the Needs of the 21st Century (Dr. Zoon)   | 6            |
| D0255                              |                   | 12/04/95                 | New Adverse Experience Reporting Requirements for<br>Licensed Biological Products   | 20           |
| D0238                              |                   | 09/19/95                 | CBER Update- Dr. Zoon's Slides  | 9            |

| <i>Hard Copy</i>         | <i>FAX ID</i> | <i>Document Date</i> | <i>Title</i>  | <i>Pages</i> |
|--------------------------|---------------|----------------------|---|--------------|
| D0221                    | 0221          | 06/26/95             | Drug Information Association (Dr. Zoon)   | 6            |
| D0217                    | 0217          | 05/01/95             | FDA Workshops on "Regulatory Policy Issues in the Development & Manufacture of Biopharmaceuticals & Other Biotechnology-Derived Products" (Dr. Zoon/Mr. Beatrice) | 18           |
| D0199                    |               | 02/16/95             | Approaches to Regulation of Hematopoietic Stem Cells  | 11           |
| D0196                    | 0196          | 01/30/95             | FDA/CBER Workshop for Licensing Blood Establishments: Computer Crossmatch   | 9            |
| D0194                    | 0194          | 01/27/95             | State of CBER 1994: The Year of Reinvention (Dr. Zoon)  | 17           |
| D0187                    | 0187          | 11/22/94             | The Role of Science in the Regulation of Biological Products (Dedication of Building 29B, Dr. Zoon)   | 7            |
| D0183                    | 0183          | 11/02/94             | CBER Update (Dr. Zoon)  | 3            |
| D0177                    | 0177          | 09/23/94             | CBER's International Activities   | 6            |
| D0176                    | 0176          | 09/19/94             | CBER Trends and the Managed Review Process (Dr. Zoon)   | 16           |
| D0159                    |               | 01/24/94             | State of CBER 1993  | 9            |
| <u><i>SOP</i></u>        |               |                      |   |              |
| D0343                    | 0343          | 12/03/96             | Centerwide Policy on Issuance of and Response to Clinical Hold Letters for Investigational New Drug Applications (OD-R-8-96, CBER)                                | 3            |
| <u><i>Talk Paper</i></u> |               |                      |   |              |
| D0939                    | 0939          | 03/07/01             | Newly Formulated DTaP (Diphtheria, Tetanus, and Pertussis) Vaccine Approved With Only Trace Amounts of Thimerosal   | 1            |
| D0892                    | 0892          | 10/03/00             | Wyeth-Ayerst Laboratories Signs Consent Decree with FDA   | 2            |
| D0852                    | 0852          | 06/23/00             | Guidance for Adverse Reactions Labeling   | 1            |
| D0824                    | 0824          | 03/10/00             | FDA Alerts Health Professionals and Consumers to Nationwide Recall of Clinipad Antiseptic Sterile Products  | 2            |
| D0823                    | 0823          | 03/08/00             | FDA's Law Enforcement in FY 1999  | 2            |
| D0817                    | 0817          | 03/07/00             | New Initiatives to Protect Participants in Gene Therapy Trials  | 3            |
| D0810                    | 0810          | 02/17/00             | First Pneumococcal Vaccine Approved For Infants and Toddlers - HHS News   | 2            |

| <i>Hard<br/>Copy</i> | <i>FAX<br/>ID</i> | <i>Document<br/>Date</i> | <i>Title</i>   | <i>Pages</i> |
|----------------------|-------------------|--------------------------|--|--------------|
| D0799                | 0799              | 01/18/00                 | FDA's Report On New Health Care Products Approved in 1999  | 7            |
| D0743                | 0743              | 08/17/99                 | New Precautionary Measures to Reduce the Theoretical Risk of New Variant CJD From Blood Products | 2            |
| D0731                | 0731              | 07/16/99                 | Serious Manufacturing Deficiencies with Abbokinase Prompt FDA Letter to Abbott Labs              | 5            |
| D0675                | 0675              | 02/12/99                 | FDA Licenses Improved Supplemental Test for Hepatitis C  | 2            |
| D0670                | 0670              | 01/29/99                 | Recall of One Lot of Tripedia Because of Subpotent Diphtheria Component                          | 2            |
| D0648                | 0648              | 11/23/98                 | FDA's FDAMA Accomplishments One Year After Enactment   | 2            |
| D0643                | 0643              | 06/19/98                 | FDA Licenses Biotech Product to Prevent Serious RSV Disease                                      | 1            |
| D0579                | 0579              | 06/05/98                 | HHS News - FDA Proposes Rules for Dissemination of Information on Off-Label Uses                 | 2            |
| D0522                | 0522              | 01/27/98                 | Alpha Therapeutic Consent Decree   | 1            |
| D0516                | 0516              | 01/14/98                 | FDA Biologics Approvals in 1997  | 2            |
| D0539                | 0539              | 11/21/97                 | FDA Modernization Act of 1997 Backgrounder   | 2            |
| D0470                | 0470              | 09/26/97                 | FDA Warns Consumers About Two Unapproved Home-Use Test Kits                                      | 2            |
| D0434                | 0434              | 07/18/97                 | FDA/CDC Warn Against Blood Donations by Those Exposed to Tick-Borne Illnesses                    | 2            |
| D0402                | 0402              | 04/24/97                 | Safety of Gelatin and Gelatin By-Products Reviewed   | 2            |
| D0359                | 0359              | 01/14/97                 | FDA Approvals in 1996 Set New Records  | 3            |

*874Documents*